



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA-2012-N-1210]

RIN 0910-AF22

Food Labeling: Revision of the Nutrition and Supplement Facts Labels

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is proposing to amend its labeling regulations for conventional foods and dietary supplements to provide updated nutrition information on the label to assist consumers in maintaining healthy dietary practices. The updated information is consistent with current data on the associations between nutrients and chronic diseases or health-related conditions, reflects current public health conditions in the United States, and corresponds to new information on consumer behavior and consumption patterns. We are proposing to update the list of nutrients that are required or permitted to be declared; provide updated Daily Reference Values and Reference Daily Intake values that are based on current dietary recommendations from consensus reports; amend requirements for foods represented or purported to be specifically for children under the age of 4 years and pregnant and lactating women and establish nutrient reference values specifically for these population subgroups; and revise the format and appearance of the Nutrition Facts label.

DATES: Submit either electronic or written comments on the proposed rule by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Submit

comments on information collection issues under the Paperwork Reduction Act of 1995 by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], (see the "Paperwork Reduction Act of 1995" section of this document). See section III of this document for the proposed effective date of a final rule based on this proposed rule.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2012-N-1210, and/or Regulatory Information Number (RIN) 0910-AF22, by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) (see the "Paperwork Reduction Act of 1995" section of this document).

#### Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

#### Written Submissions

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5360 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA-2012-N-1210 and RIN 0910-AF22 for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Blakeley Fitzpatrick, Center for Food Safety and Applied Nutrition (HFS-830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-5429, email: [NutritionProgramStaff@fda.hhs.gov](mailto:NutritionProgramStaff@fda.hhs.gov).

With regard to the information collection: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400T, Rockville, MD 20850, [Domini.bean@fda.hhs.gov](mailto:Domini.bean@fda.hhs.gov).

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Executive Summary

Purpose of the Regulatory Action

FDA is proposing to amend the regulations for the nutrition labeling of conventional foods and dietary supplements to assist consumers in maintaining healthy dietary practices.

Following the passage of the Nutrition Labeling and Education Act (NLEA) of 1990 (the 1990 amendments) (Pub. L. 101-535), which added section 403(q) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 343(q)), we issued various regulations related to nutrition information on food labels, including the declaration of nutrients, the format for nutrition labeling, reference values for use in declaring the nutrient content, and allowances for certain specified products to be exempt from nutrition labeling (§ 101.9 (21 CFR 101.9)). In

addition, following the passage of the Dietary Supplement Health and Education Act (DSHEA) of 1994 (Pub. L. 103-417 and 21 U.S.C. 321(ff)), we amended our food labeling regulations to establish requirements for nutrition labeling of dietary supplements (§§ 101.9(j)(6) and 101.36). Section 403(q) of the FD&C Act specifies certain nutrients to be declared in nutrition labeling, and authorizes the Secretary of Health and Human Services to require other nutrients to be declared if the Secretary determines that a nutrient will provide information regarding the nutritional value of such food that will assist consumers in maintaining healthy dietary practices. The Secretary also has discretion under section 403(q) of the FD&C Act to remove, by regulation and under certain circumstances, nutrient information that is otherwise explicitly required in food labeling under this section.

We are proposing to revise our regulations to provide updated nutrition information on the label and improve how the nutrition information is presented to consumers, in light of current scientific evidence, dietary recommendations of most recent consensus reports, and public comments received in response to advance notices of proposed rulemaking. FDA invites comment on its use of the most recent consensus reports and whether the information and data on which FDA relies from such reports for proposed changes is consistent with current scientific information.

#### Summary of the Major Provisions of the Regulatory Action in Question

We discuss the need to update the Nutrition Facts and Supplement Facts labels in section I.B., and our scientific considerations for mandatory and voluntary declaration of nutrients are presented in section I.C. In sections II.A. through II.K., we discuss provisions related to the declaration, reference values, analytical methods, and definitions of nutrients that are required or permitted to be declared on the Nutrition Facts label of conventional foods, whereas

corresponding changes to the Supplement Facts label of dietary supplements are presented in section II.L. We present our considerations related to the format of the Nutrition Facts and Supplement Facts labels in section II.M., and discuss issues related to compliance with the proposed requirements in section II.N. Some of the key proposed actions and considerations of the proposed rule are highlighted in this document.

Among other amendments related to declaration of nutrients, we are proposing to remove the declaration of "Calories from fat" because current science supports a view that the type of fat is more relevant than overall total fat intake in increased risk of chronic diseases. In addition, removal of the "calories from fat" disclosure had no effect on consumers' judgments of product healthfulness, accuracy in identifying nutrient contents of products, or perceptions in FDA's consumer research.

Considering current science and recommendations related to added sugars, we are also proposing to require the declaration of "added sugars," that will provide consumers with information they need to implement the dietary recommendations of the Dietary Guidelines for Americans, 2010 (2010 DGA).

We are also proposing to update the list of vitamins and minerals of public health significance. We currently require the mandatory declaration of percent Daily Values (DVs) of vitamins A and C, calcium and iron. We analyzed the nutrient inadequacy for vitamins and minerals based on biomarker data and total dietary intake (conventional foods and dietary supplements) using National Health and Nutrition Examination Survey (NHANES) data and other factors for mandatory and voluntary declaration discussed in section I.C. to determine which essential vitamins and minerals should be included as nutrients of public health significance. Based on this analysis, we are not proposing any changes to the current

requirement for mandatory declaration of calcium and iron. In addition, we are proposing to require the declaration of vitamin D and potassium, and to permit, rather than require, the declaration of vitamins A and C.

With respect to reference values used to declare percent DVs of nutrients, since 1993, new reports from the Institute of Medicine (IOM) and other consensus and policy reports (for example, the 2010 DGA and the Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans) have been published that update the quantitative intake recommendations of nutrients as well as their association with chronic disease and health-related conditions. We are using these new data to update, as appropriate, the reference values used in the declaration of percent DVs of nutrients on the Nutrition Facts and Supplement Facts labels.

Among other amendments to reference values, we are proposing an updated reference value for the declaration of percent DV for sodium from the current value of 2,400 mg (milligrams) to 2,300 mg based on a consideration of current science and IOM's report that set Dietary Reference Intakes (DRIs) for sodium, including a Tolerable Upper Intake Level of 2,300 mg/day (d) as a reference intake level not to exceed.

A primary change that we are proposing to the format of the Nutrition Facts and Supplement Facts labels is to increase the prominence of the "Calories," numeric value of calories, "Servings per container," and numeric value of servings per container declarations. Research suggests that these proposed changes may increase consumers' attention to the information, and in certain situations, help consumers to accurately identify the number of calories in a product. We are also proposing to move the "% DV" to the left side of the label in order to highlight the information for consumers. We are also proposing to remove the requirement for the footnote table listing the reference values for certain nutrients for 2,000 and

2,500 calorie diets. We intend to continue to perform consumer research during this rulemaking process to evaluate how variations in label format may affect consumer understanding and use of the Nutrition Facts label. We intend to publish the results of our research for public review and comment.

CURRENT LABEL

<b>Nutrition Facts</b>	
Serving Size 2/3 cup (55g)	
Servings Per Container About 8	
<b>Amount Per Serving</b>	
<b>Calories</b> 230	Calories from Fat 40
<b>% Daily Value*</b>	
<b>Total Fat</b> 8g	<b>12%</b>
Saturated Fat 1g	<b>5%</b>
<i>Trans</i> Fat 0g	
<b>Cholesterol</b> 0mg	<b>0%</b>
<b>Sodium</b> 160mg	<b>7%</b>
<b>Total Carbohydrate</b> 37g	<b>12%</b>
Dietary Fiber 4g	<b>16%</b>
Sugars 1g	
<b>Protein</b> 3g	
Vitamin A	10%
Vitamin C	8%
Calcium	20%
Iron	45%
* Percent Daily Values are based on a 2,000 calorie diet. Your daily value may be higher or lower depending on your calorie needs.	
	Calories: 2,000    2,500
Total Fat	Less than 65g    80g
Sat Fat	Less than 20g    25g
Cholesterol	Less than 300mg    300mg
Sodium	Less than 2,400mg    2,400mg
Total Carbohydrate	300g    375g
Dietary Fiber	25g    30g

PROPOSED LABEL

<b>Nutrition Facts</b>	
<b>8 servings per container</b>	
Serving size	2/3 cup (55g)
<b>Amount per 2/3 cup</b>	
<b>Calories</b>	<b>230</b>
<b>% DV*</b>	
<b>12%</b>	<b>Total Fat</b> 8g
<b>5%</b>	<b>Saturated Fat</b> 1g
	<i>Trans Fat</i> 0g
<b>0%</b>	<b>Cholesterol</b> 0mg
<b>7%</b>	<b>Sodium</b> 160mg
<b>12%</b>	<b>Total Carbs</b> 37g
<b>14%</b>	<b>Dietary Fiber</b> 4g
	Sugars 1g
	<b>Added Sugars</b> 0g
	<b>Protein</b> 3g
10%	<b>Vitamin D</b> 2mcg
20%	<b>Calcium</b> 260mg
45%	<b>Iron</b> 8mg
5%	<b>Potassium</b> 235mg
* Footnote on Daily Values (DV) and calories reference to be inserted here.	

We are also proposing to require the maintenance of records to support the declarations of certain nutrients under specified circumstances. Currently, there are no analytical methods that can distinguish between dietary fiber (soluble and insoluble fiber) and non-digestible carbohydrates that do not meet the definition of dietary fiber; added and naturally occurring sugars; the various forms of vitamin E; or folate and folic acid and there are no analytical methods that can determine the amount of added sugar in specific foods containing added sugars alone or in combination with naturally occurring sugars, where the added sugars are subject to fermentation. Therefore, for products that contain non-digestible carbohydrates that do not meet the definition of dietary fiber, more than one source of sugar, added sugars that undergo fermentation, various forms of vitamin E, or folate and folic acid, we are proposing that manufacturers must make and keep certain written records to verify their declarations of each of

these nutrients in the labeling of the food associated with such records. We are also proposing that records must be kept for a period of at least 2 years after introduction or delivery for introduction of the food into interstate commerce and may be kept as original records, as true copies, or electronically, and manufacturers must provide those records to us for inspection and copying upon request during an inspection.

We anticipate that consumer education efforts would be needed to help with consumer understanding and use of information presented under the changes to the Nutrition Facts and Supplement Facts labels proposed in this rule. We plan to use the results of our consumer research to help inform our future actions on this issue.

Finally, we are proposing an effective date of 60 days after the date of the final rule's publication in the Federal Register with a compliance date 2 years after the effective date. We invite comment on the proposed compliance date. In addition to the proposed compliance date, we invite comment on various other issues, as summarized in section XI.

#### Costs and Benefits

We have developed one comprehensive preliminary regulatory impact analysis that presents the benefits and costs of this proposed rule as well as the proposed rules entitled Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed at One Eating Occasion; Dual Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments taken together. The cumulative impact of these two nutrition labeling proposals, taken as a whole, is shown in the following table.

Summary of Costs and Benefits  
(in billions of 2011 \$)

	Benefits	Costs	Net Benefits
Present Value (PV)			
3%	\$31.4	\$2.3	\$29.1
7%	\$21.1	\$2.3	\$18.8
Annualized (3% PV Amount)			
3%	\$2.0	\$0.2	\$1.8
Annualized (7% PV Amount)			
7%	\$1.9	\$0.2	\$1.7

Notes: Compliance period is 24 months. Costs include relabeling and reformulation costs, which are one-time costs, as well as recordkeeping costs, which recur. Present values of relabeling and reformulation costs are equivalent at 3 or 7 percent because we conservatively assume that these one-time costs are incurred upon publication of the rule instead of at the end of the compliance period. Recordkeeping costs, because of their recurring nature, differ by discount rate; however, such costs comprise a very small percentage of total costs.

### I. Background

The 1990 amendments added section 403(q) to the FD&C Act, which specifies, in part and with certain exceptions, that food is deemed misbranded unless its label or labeling bears nutrition information for certain nutrients. To implement the 1990 amendments, on January 6, 1993, FDA issued several rules, including "Food Labeling: Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label (the 1993 nutrient content final rule)"; "Food Labeling; Reference Daily Intakes and Daily Reference Values (1993 RDI/DRV final rule)"; and "Food Labeling: Serving Sizes", to modify how nutrition information is presented on food labels (58 FR 2079; 58 FR 2206; 58 FR 2229, respectively). FDA published regulations related to: (1) Declaration of nutrients on food labeling, including nutrients that are required or permitted to be declared and the format for such declaration; (2) label reference values for use in declaring the nutrient content of a food on its label or labeling; (3) two types of reference values, Reference Daily Intakes (RDIs) for vitamins and minerals and

Daily Reference Values (DRVs) for certain nutrients, which are used to declare nutrient contents as percent DVs on the Nutrition Facts label; (4) exemptions for certain specified products; and (5) a simplified form of nutrition labeling and the circumstances in which such simplified nutrition labeling can be used. (See § 101.9.) Elsewhere in this issue of the Federal Register, we are publishing a proposed rule that will amend the definition of a single-serving container, require dual column labeling for certain containers, update the reference amounts customarily consumed and serving sizes for several food product categories and amend the serving size for breath mints.

In 1994, DSHEA became law. Among other things, DSHEA amended section 403(q)(5)(F) of the FD&C Act by adding specific requirements that relate to the labeling of dietary supplement products. Accordingly, we amended our food labeling regulations to establish requirements for nutrition labeling of dietary supplements (§§ 101.9(j)(6) and 101.36).

The regulatory history, our rationale for existing requirements, and FDA activities related to nutrition labeling of foods and dietary supplements are described in Reference 1.

#### A. Legal Authority

We are proposing to update the Nutrition Facts label and Supplement Facts label, as set forth in this proposed rule, consistent with our authority in section 403(q) of the FD&C Act. Section 403(q)(1) of the FD&C Act states that a food shall be deemed to be misbranded if, with certain exceptions, it fails to bear nutrition labeling and identifies specific nutrient and calorie information required in labeling. Section 403(q)(2)(A) of the FD&C Act provides the Secretary, and by delegation, FDA, with discretion to require by regulation nutrition information about nutrients other than those specified in section 403(q)(1) of the FD&C Act to assist consumers in maintaining healthy dietary practices. Section 403(q)(2)(B) of the FD&C Act permits the

Secretary, and by delegation, FDA, to remove information relating to a nutrient required by section 403(q)(1) or 403(q)(2)(A) of the FD&C Act if the Secretary determines that it is not necessary to assist consumers in maintaining healthy dietary practices. Consistent with these authorities, we are proposing to revise certain nutrient declarations in the Nutrition Facts label and Supplement Facts label. In addition, FDA's authority includes section 2(b)(1) of the 1990 amendments (21 U.S.C. 343 note). Specifically, section 2(b)(1)(A) of the 1990 amendments requires nutrition label information be conveyed in a manner that enables the public to readily observe and comprehend the information and to understand its relative significance in the context of a total daily diet. Such section states that such information should be consistent with current scientific knowledge about nutrients and health. We are proposing changes to DVs (RDIs and DRVs, as applicable) for some nutrients, which values are used to calculate the percent DV for use on food labels. The use of reference values based on current science and the use of such values to calculate the percent DV assists consumers in comprehending the nutrition information and its relative significance in a total daily diet. We are also proposing changes to the format pertaining to information on the percent DV value. Further, section 2(b)(1)(C) of the 1990 amendments stipulates that regulations "shall permit the label or labeling of food to include nutrition information which is in addition to the information required by such section 403(q) [of the FD&C Act] and which is of the type described in subparagraph (1)( or (2) of such section . . . ." We are proposing changes to the voluntary declaration of certain nutrients in the Nutrition Facts label consistent with such authority.

Other relevant authorities include sections 701(a), 403(a)(1) and 201(n) of the FD&C Act (21 U.S.C. 371(a), 21 U.S.C. 343(a)(1), and 21 U.S.C. 321(n), respectively). Under section 701(a) of the FD&C Act, the Agency may issue regulations for the efficient enforcement of the

FD&C Act in order to "effectuate a congressional objective expressed elsewhere in the Act" (Association of American Physicians and Surgeons, Inc. v FDA, 226 F. Supp. 2d 204 (D.D.C. 2002) (citing Pharm. Mfrs. Ass'n. v FDA, 484 F. Sup. 1179, 1183 (D. Del. 1980).)

We are relying on our authority under sections 403(q), 403(a), 201(n) and 701(a) of the FD&C Act, to propose record requirements to support nutrient declarations in labeling for added sugars, dietary fiber, soluble fiber, insoluble fiber, vitamin E, and folate/folic acid, under certain circumstances, so that we can determine compliance with labeling requirements and take enforcement action, as needed. For these nutrients, as explained in section II.N., there is no AOAC official method of analysis of AOAC International or other reliable or appropriate analytical procedure, otherwise required by § 101.9(g), available for FDA to quantify the declared amount of the nutrient, under certain circumstances. Section 101.9(g) sets forth the standards for accuracy of the amount statements of nutrients on food labels. Failing to accurately state the amounts of nutrients on the label under § 101.9(g) would result in a product being misbranded. Under section 403(q) of the FD&C Act, a food must bear, in its label or labeling, the amount of the nutrient the food contains. Moreover, the nutrient declaration must be truthful and not misleading under sections 403(a)(1) and 201(n) of the FD&C Act. Thus, when a food product contains dietary fiber (whether soluble, insoluble, or a combination of both) and added non-digestible carbohydrate(s) that does not meet the definition of dietary fiber, we are proposing to require manufacturers to make and keep certain written records to verify the amount of added non-digestible carbohydrate that does not meet the definition of dietary. When vitamin E is present in a food as a mixture of all rac- $\alpha$ -tocopherol acetate and RRR-  $\alpha$ -tocopherol, we are proposing to require manufacturers to make and keep written records to verify the amount of all rac- $\alpha$ -tocopherol acetate added to the food and RRR- $\alpha$ -tocopherol in the finished food. When a

mixture of folate and folic acid is present in a food, we are proposing to require manufacturers to make and keep records to verify the amount of folic acid added to the food and folate in the finished food. When added sugars as well as naturally occurring sugars are present in a food, we are proposing to require manufacturers to make and keep records to verify the declared amount of added sugars in the food. Finally, we are proposing to require manufacturers to make and keep records to verify the declared amount of added sugars in specific foods, alone or in combination with naturally occurring sugars, where the added sugars are subject to fermentation.

The proposed record requirements for these nutrients, under the circumstances described, are designed to ensure that the nutrient declarations are accurate, truthful and not misleading, based on information known only to the manufacturer, and to facilitate efficient and effective action to enforce the requirements when necessary. Our authority to establish records requirements has been upheld under other provisions of the FD&C Act where FDA has found such records to be necessary (National Confectioners Assoc. v Califano, 569 F.2d 690, 693-94 (D.C. Cir. 1978)). The records we propose to require are only for foods for which an adequate analytical method is not available. The records would allow us to verify the declared amount of each of these nutrients and that such amount is truthful and not misleading. Thus, the proposed records requirements would help in the efficient enforcement of the FD&C Act.

The authority granted to FDA under sections 701(a), 403(q), 403(a)(1) and 201(n) of the FD&C Act not only includes authority to establish records requirements, but also includes access to such records. Without such authority, the nutrient declarations for these specific nutrients that FDA has determined are necessary to assist consumers in maintaining healthy dietary practices under section 403(q)(2)(A) of the FD&C Act are, practically speaking, not enforceable. Without access to such records, FDA would not know whether the amount declared on the label or in the

labeling of each these nutrients, under the circumstances described, is truthful and not misleading under sections 403(a)(1) and 201(n) of the FD&C Act. The introduction or delivery for introduction into interstate commerce of a misbranded food is a prohibited act under section 301(a) of the FD&C Act (21 U.S.C. 331(a)). Thus, to determine whether the food is misbranded and the manufacturer has committed a prohibited act, we must have access to the manufacturer's records that we are requiring be made and kept under sections 403(q), 403(a)(1), 201(n) and 701(a) of the FD&C Act. Failure to make and keep records and provide the records to FDA, as described in proposed § 101.9(g)(10) and (g)(11), would result in the food being misbranded under sections 403(q) and 403(a)(1) of the FD&C Act.

#### B. Need to Update the Nutrition Facts and Supplement Facts Labels

FDA first issued regulations related to the Nutrition Facts label in 1993. We have not updated the Nutrition Facts label since the 2003 trans fat rulemaking (68 FR 41434; July 11, 2003) or established new or updated DVs for nutrients since 1995 (60 FR 67164; December 28, 1995). Since that time, the public health profile of the U. S. population has changed (e.g., increase in obesity), new information has become available about nutrient definitions (e.g., vitamin E), reference intake values, and analytical methods, and new dietary recommendations (see section I.B.2.) have been published. As a result, we are reconsidering what nutrients we should require or permit to be listed on the Nutrition Facts label and what nutrient reference intake values we should use as a basis for calculating the percent DVs in food labeling. We also considered corresponding changes to the Supplement Facts labels. We discuss specific nutrient declarations in greater detail in section II. Section I.B. includes an overview of information we considered when forming our tentative conclusions, including scientific and technical data and recommendations, citizen petitions submitted to us, and public comments to previous requests

for comment in advance notices of proposed rulemaking on topics related to this proposed rule. We also considered the role of nutrition labeling to assist consumers in maintaining healthy dietary practices and consumers' use and understanding of the Nutrition Facts label.

#### 1. Rates of Chronic Disease

Chronic diseases, such as heart disease, cancer and stroke are the leading causes of death and disability in the United States, and account for 70 percent of all deaths in the United States (Ref. 2). In 2005, 133 million Americans, almost one out of every two adults, had at least one chronic illness (Ref. 2). An estimated 37 percent of Americans suffer from cardiovascular disease (CVD) (Ref. 3), 11.3 percent of the population 20 years and older has diabetes, 35 percent of adults has pre-diabetes (Ref. 4), and 41 percent of the population is predicted to be diagnosed with cancer during their lifetime (Ref. 5). While the causes of these chronic diseases are multifactorial, poor diet is a contributing factor associated with morbidity and mortality (Ref. 6). Many nutrients are associated with chronic disease risk. For example, diets low in saturated fat and cholesterol, and/or sodium are associated with a decreased risk of CVD (58 FR 2739; January 6, 1993, and 58 FR 2820; January 6, 1993). Adequate or increased intake of calcium and vitamin D may decrease the risk of osteoporosis (73 FR 56477; September 29, 2008).

Obesity rates have increased dramatically over the last three decades. Between 1976 and 1980 and 2007 and 2008, obesity rates increased more than twofold (from 15 to 34 percent) in adults and more than threefold (from 5 to 17 percent) among children and adolescents (Refs. 6 to 8). Data published by the U. S. Centers for Disease Control and Prevention (CDC) indicate that 68 percent of adults and about 32 percent of children aged 2 to 19 years in the U. S. population are overweight or obese (Refs. 7 and 8). Excessive body weight is a risk factor for chronic diseases such as heart disease, some forms of cancer, and type II diabetes (Ref. 9). The 2010

DGA affirmed the role of over consumption of calories and physical inactivity as the primary risk factors contributing to an epidemic of overweight and obesity in this country, and urged for a focus on improved nutrition and physical activity choices among Americans (Ref. 6).

Elevated blood pressure, an important risk factor for CVD (Ref. 10), affects about one-third of the U. S. adult population (Ref. 2). High intakes of sodium are directly associated with elevated blood pressure (Ref. 10). Average sodium intake for the U. S. population 4 years of age and older is approximately 3,650 mg/d (Ref. 11). Almost all Americans consume more sodium than the levels recommended by the 2010 DGA (Ref. 12)

Furthermore, while concerns in recent years have largely shifted away from nutritional deficiencies, some population subgroups may consume excess calories but still consume inadequate amounts of certain micronutrients such as iron, vitamin D, calcium and potassium (see section II.H.).

The mandatory declaration of nutrients that have public health significance, the use of updated DVs based on current scientific evidence, and the use of a format for the Nutrition Facts label to assist with consumer use and understanding can help consumers make informed food choices to consume a nutritionally adequate diet while monitoring calorie intake and lowering their risk of some chronic diseases.

## 2. Dietary Recommendations, Consensus Reports, and National Survey Data

a. IOM Dietary Reference Intakes Reports (IOM DRI Reports)--In 1994, the Food and Nutrition Board (FNB) of the Institute of Medicine (IOM) identified principles for the development of a new set of reference values that could expand and replace the IOM's Recommended Dietary Allowances (RDAs) of 1989 (Refs. 13 and 14). A comprehensive review and application of a growing body of nutritional science research resulted in the development of

a set of reference values, collectively known as DRIs, published from 1997 to 2010 (Ref. 15). The DRIs represent a shift in the way that reference values are established or intended for use. In contrast to previous editions of RDAs (e.g., the 1968 and 1989 RDAs), which involved establishing single values for each nutrient with appropriate adjustments for age, sex and physiological status, the new DRI framework consisted of four categories of reference values. These categories include the Estimated Average Requirement (EAR), RDA, Adequate Intake (AI) and Tolerable Upper Intake Level (UL). For macronutrients--carbohydrates, fats, and protein--the IOM developed a new set of reference values called the Acceptable Macronutrient Distribution Ranges (AMDRs).

The EAR is the average daily nutrient intake level that is estimated to meet the requirements of half of the healthy individuals in a particular life stage and gender group. EARs are used for assessing the statistical probability of adequacy of nutrient intakes of groups of people. The RDA is an estimate of the average intake level that meets the nutrient requirements of nearly all (97 to 98 percent) healthy individuals in a particular life stage and gender group. The RDA is set using the EAR. In general, the RDA is the EAR plus two times the standard deviation of the EAR. The RDA is used to plan nutrient intakes for individuals to ensure a low probability of inadequacy. Nutrients with EARs and RDAs include carbohydrate, protein, vitamin A, vitamin C, vitamin E, thiamin, riboflavin, niacin, vitamin B<sub>6</sub>, folate, vitamin B<sub>12</sub>, copper, iodine, iron, magnesium, phosphorus, selenium, zinc, calcium and vitamin D.

An AI is the level determined for an essential nutrient or a nutrient that is beneficial for human health when there is insufficient evidence to calculate an EAR for that nutrient, and therefore insufficient evidence on which to establish an RDA. AIs can be based on a variety of data, including scientific evidence about the essentiality of a nutrient (i.e., choline, biotin,

fluoride), experimental data on risk reduction of chronic disease (i.e., dietary fiber, potassium), and median intakes of a nutrient using national survey data (i.e., vitamin K, pantothenic acid, chromium, manganese, linoleic acid, and [alpha]-linolenic acid). Although there is less certainty about an AI value than about an RDA value, the AI is similarly designed to cover the needs of nearly all individuals. The IOM Dietary Planning Report and Dietary Assessment Report noted that "the AI should be used with less confidence if it has not been established as the mean intake of a healthy group."

The UL is the highest average daily intake level likely to pose no risk of adverse health effects for nearly all people in a particular group. The UL is not intended to be a recommended level of intake. The UL is used to assess the risk of adverse health effects from excessive nutrient intake. As intake above the UL increases, so does the potential for risk of adverse health effects. Nutrients with ULs include vitamin A, vitamin C, vitamin D, vitamin E, niacin, vitamin B<sub>6</sub>, folate, choline, calcium, copper, fluoride, iodine, iron, magnesium, manganese, molybdenum, phosphorus, selenium, zinc, sodium, and chloride.

Moreover, while the previous RDAs primarily focused on reducing the incidence of diseases of nutrient deficiency in the population, the DRIs now take into consideration data on chronic disease risk, such as heart disease, and developmental abnormalities, such as teratogenicity, rather than only the signs of deficiency. Finally, where sufficient data exist, the DRIs take into account the potential benefit or risk to health of substances that are not essential (such as dietary fiber and fluoride) that are in addition to the macronutrients of total carbohydrate, protein, and fat, and the micronutrient vitamins and minerals permitted or required on the Nutrition Facts label (Ref. 15). Beginning in 1997, the IOM began publishing its DRIs for those vitamins, minerals, and macronutrients that are essential in humans or provide a beneficial

role in human health (Refs. 16 to 22). In addition, the IOM also set AMDRs for carbohydrates, fat, and protein (Ref. 23). The AMDR for a macronutrient is based on the amount of the macronutrient that is associated with a reduced risk of chronic disease while providing adequate intakes of essential nutrients. The AMDR is expressed as a range of percent energy intake (e.g., 20 to 35 percent of calories from total fat for adults over 18 years of age). The DRIs and AMDRs were set for the following life stage groups: Infants (0 to 6 and 7 to 12 months); toddlers (1 to 3 years); boys and girls (4 to 8 years); adolescent boys and girls (9 to 13 and 14 to 18 years); adult men and women (19 to 30, 31 to 50, 51 to 70, and greater than 70 years); and pregnant and lactating women.

b. IOM Dietary Fiber Report--In 2001, the IOM Panel on the Definition of Dietary Fiber (the IOM Dietary Fiber Panel) responded to our request to provide definitions for dietary fiber based on its role in human physiology and health. The IOM Dietary Fiber Panel developed two categories of definitions of fiber: "Dietary Fiber" and "Added Fiber" in its report Dietary Reference Intakes: Proposed Definition of Dietary Fiber (the IOM Dietary Fiber Report) (Ref. 24).

c. IOM Dietary Assessment Report--In 2000, the IOM Subcommittee on Interpretation and Uses of Dietary Reference Intakes (IOM uses Committee) published the report, DRIs Application in Dietary Assessment (IOM Dietary Assessment report) on how to use the DRIs for dietary assessment of individuals and groups.

d. IOM Labeling Report--In 2003, the IOM Committee on nutrition labeling (IOM Labeling Committee) considered how the DRIs can be used to develop appropriate reference values for nutrition labeling and published its report, co-funded by FDA, DRI Guiding Principles

for Nutrition Labeling and Fortification (the IOM Labeling Report) (Ref. 25), with the goal of having an updated nutrition label that consumers can use to make informed dietary choices.

e. IOM Dietary Planning Report--In 2003, the IOM Subcommittee on interpretation and uses of DRIs (IOM Uses Committee) published a report, DRIs Application in Dietary Planning (IOM Dietary Planning Report) (Ref. 26) on how to use the DRIs for planning intakes of individuals and groups. This report discusses the use of the DRIs for food and supplement labels.

f. IOM Sodium Strategies Report--In 2008, the IOM convened a Committee on Strategies to Reduce Sodium Intake in the United States to address a Congressional request for recommendations about various means that could be employed to reduce dietary sodium intake to levels recommended by the 2005 DGA (less than 2,300 mg/d and no more than 1,500 mg/d for African-Americans, people with hypertension, and middle-aged and older adults). The Committee's report, Strategies to Reduce Sodium Intake in the United States (IOM Sodium Strategies Report), published in 2010, among other strategies, discusses how the labeling of sodium on foods can serve as a supporting strategy for reducing sodium intake (Ref. 27).

g. IOM Front-Of-Package Nutrition Rating Systems and Symbols Phase I and Phase II Reports--In 2010, the IOM Committee on Front-of-Package (FOP) Nutrition Rating Systems and Symbols reviewed the existing FOP systems and their underlying nutrition criteria. In the Phase I report, the IOM identified the nutrients for which there was sufficient evidence of their role in chronic disease risk and which should be included in a FOP label (Ref. 28). In 2012, the IOM published its phase II report that recommended developing a single standardized FOP rating system and updated their recommendations for nutrients to be included on the FOP label (Ref. 29).

h. IOM Sodium Intake in Populations Report- In 2012 the IOM convened a Committee to review and assess the benefits and adverse outcomes (if any) of reducing the sodium intake in the population, particularly in the range of 1,500 to 2,300 mg/d. The Committee was also asked to specifically emphasize relevant subgroups in the analysis including those 50 years of age and older, African Americans, and those with diabetes, chronic kidney disease, and congestive heart failure. The Report was published in May of 2013 and focused its findings and conclusions on evidence for associations between sodium intake and the risk of CVD-related events and mortality.

i. Dietary Guidelines for Americans (DGA), 2010--The 2010 DGA, developed jointly by the U. S. Department of Agriculture (USDA) and the U. S. Department of Health and Human Services (HHS), provide several key recommendations including recommendations about dietary patterns, as well as quantitative intake recommendations with respect to micronutrients and macronutrients, most of which are based on the IOM DRI reports (Ref. 6). In a few cases, the 2010 DGA provided quantitative intake recommendations for certain nutrients (i.e., cholesterol and saturated fat) that were not provided by the IOM DRI reports (Ref. 6). The 2010 DGA emphasized the importance of meeting food and nutrient recommendations while balancing calorie needs (Ref. 6). More information regarding the scientific basis that informed the development of the 2010 DGA can be found in the Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans, 2010 (2010 DGAC) (Ref. 30). An important note related to the 2010 DGA is the specified intended audience for its recommendations (Ref. 6). From the 1980s until 1995, the DGAs were targeted toward healthy Americans and designed to provide advice to healthy individuals about food choices that promote health and prevent disease (Refs. 31 to 34). In 2000, the recommendations specified an

audience of "healthy children ages 2 years and older and adults of any age," and the 2005 DGA provided recommendations for the "general public age 2 years and older." (Refs. 35 and 36). While the DGAs have always taken into account the needs of subpopulations, the most recent 2010 DGA goes beyond the traditional target of a "healthy" audience to provide chronic disease," noting "the reality that a large percentage of Americans are overweight or obese and/or at risk of various chronic diseases" (Ref. 6).

j. National Health and Nutrition Examination Survey (NHANES)--The NHANES provides the primary source of information on the health and nutritional status of adults and children in the United States. The survey examines a nationally representative sample of about 5,000 persons each year. These persons are located in counties across the country. The survey combines interviews, which include demographic, socioeconomic, dietary, and health-related questions, and physical examinations, which consist of medical, dental, and physiological measurements, as well as laboratory tests administered by highly trained medical personnel (Ref. 37)

### 3. Consumer Use and Understanding of the Nutrition Facts Label

The Nutrition Facts label is intended to help consumers make informed food choices and maintain healthy dietary practices. Consumers became increasingly aware of the new label in the years following implementation of the 1990 amendments, and reported using food labels more often in their purchasing decisions compared to their use before the introduction of the Nutrition Facts label (Ref. 38).

Data from a nationally representative sample of U. S. adults collected through FDA's Health and Diet Surveys suggest that the frequency of food label use among consumers progressively increased between 2002 and 2008 (Refs. 39 to 41). For example, the percentage of

consumers reporting that they "often" read a food label the first time they purchase a food product rose from 44 percent in 2002 to 54 percent in 2008. Among those indicating they read food labels when purchasing a product for the first time, two-thirds of them in 2008 reported using the label to see how high or low the food was in calories, salt, vitamins or fat, while more than half said they used labels to get a general idea of the nutritional content of the product. A similar increase in reported use of food labels has also been shown using data from the National Health and Nutrition Examination Surveys 2007-2008 and 2009-2010. The percent of working age adults that reported using the Nutrition Facts Panel (NFP) always or most of the time when shopping for food increased to 42% in 2009-2010 from 34% in 2007-2008. Among older adults the percentage increased to 57% in 2009-2010 from 51% in 2007-2008. (Ref. 42).

Consumer research data suggest that, despite the widespread use of food labels, certain elements of the Nutrition Facts label may need improvement. For example, some consumers have difficulty understanding the concept of percent DV (Refs. 43 and 44) or are confused by the label footnote that lists DVs for certain nutrients based on a 2,000 and 2,500 calorie diet (Ref. 45).

Section 2(b)(1)(A) of the 1990 amendments mandated that FDA regulations implementing section 403(q) of the FD&C Act require that nutrition labeling must be conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet. In particular, the percent DV of a nutrient present in food is declared on food labels to help consumers understand the relative significance of nutrition information in the context of a total daily diet, compare the nutritional values of food products, and to plan general diets (58 FR 2206 at 2213; January 6, 1993). We also noted that the percent DV information advises the consumer

how much of a recommended intake of that nutrient is provided by the food (58 FR 2079 at 2123; January 6, 1993). We developed the term "Daily Value" to refer to all reference values on the nutrition label (DRVs and RDIs). We noted that some of the reference values were intended to guide consumers relative to maximum intakes (DRVs) (e.g., saturated fat), while others were intended to serve as the basis for planning general diets to meet nutrient requirements (RDIs) (e.g., vitamin C) (58 FR 2079 at 2124). Our research at the time showed that the term "Daily Value" was generally understood by consumers as a point of reference (58 FR 2079 at 2125).

In order to determine a nutrition labeling format that could be used most effectively by consumers, we conducted consumer research and evaluated research conducted by others in considering requirements for the nutrition label format (58 FR 2079 at 2115-2121). When available, we used empirical data on how consumers use and understand the label in proposing what information should be declared on the label and how. We used focus group data to inform what we would test in experimental studies, but did not rely on such data to make policy decisions. Several comments to the ANPRMs submitted focus group data. However, we are not relying on focus group data for the proposed changes to the Nutrition Facts label because focus groups do not yield meaningful quantitative findings and are not able to support conclusions about the relationships between the presentation of label information and consumer responses. As such, they cannot be used to drive the development of policies, programs, and services. Policy makers and educators can use focus groups findings to test and refine their ideas, but should then conduct further research before making important decisions such as adopting new policies and allocating or redirecting significant resources to support these policies.

We have completed one study that examined dual-column labels and ways to increase prominence of certain label information, and intend to continue to perform research during this

rulemaking process to evaluate how variations in label format may affect consumer understanding and use of the Nutrition Facts label. Issues to be addressed include how a declaration of "Added Sugars" and alternative footnote statement may influence consumer use of the label.

The overall goal of these studies is to assess a consumer's ability to use the Nutrition Facts label and assess a consumer's preferences related to proposed modifications of the Nutrition Facts label format. In addition, the studies will help us focus our efforts on consumer education as well as enhance our understanding of whether modifications to the Nutrition Facts label format could help consumers make more informed choices based on their perceptions of the nutritional attributes and overall healthfulness of a food product. (See also discussion in section II.M.)

#### 4. Other Relevant Considerations

In developing this proposed rule, we considered changes that would assist consumers in maintaining healthy dietary practices and recognize that it is important for the updated Nutrition Facts label to be useful and relevant to the American population. While the Nutrition Facts label information has never been nor is it now targeted to individuals with acute or chronic disease, we are considering the large portion of the U. S. population that is at risk for chronic disease in proposing changes to the label's content and format. The population at risk for chronic disease includes those who are overweight, and therefore at increased risk of certain chronic diseases, or those who are obese, leading to a variety of complications including diabetes and CVD. This approach is consistent with the new IOM DRIs, which are for healthy individuals, including those at-risk of disease, but not for individuals with acute or chronic disease or nutrient deficiencies (Ref. 15). Similarly, the DGAs are for Americans ages 2 years and older, including

those at risk of chronic disease. While consumers with acute or chronic disease, such as obesity, CVD, or diabetes, may be able to use quantitative information on the label to follow advice they have received from a health care professional concerning their conditions, the nutrient declarations and percent DVs on the label are to help consumers make more informed choices to consume a healthy diet and not intended for the clinical management of an existing disease. In addition, we recognize the importance of federal regulations reflecting the most current science. In developing this proposed rule, we considered new scientific evidence and dietary recommendations about the relationship between nutrients and health.

Finally, we recognize that the goal of assisting consumers in maintaining healthy dietary practices requires that we consider certain practicalities. For example, as we noted in the 1993 nutrient content final rule (58 FR 2079 at 2107), while the 1990 amendments permit the Secretary of Health and Human Services to include in the Nutrition Facts label any information about a nutrient that will assist consumers in maintaining healthy dietary practices, there is not room on the label for all information that may be related to maintaining healthy dietary practices. Space constraints on the label of most foods make declaring all essential nutrients impractical. In addition, having a large amount of information on the label could interfere with consumers' abilities to use the information that has the greatest public health significance. Therefore, not only are we aware of the amount and format of mandatory information on the label, but we recognize that limits to the voluntary information are necessary, so that voluntary information does not clutter the label, does not mislead, confuse, or overwhelm the consumer, and does not take away prominence of and emphasis on the required information.

## 5. Citizen Petitions

Since 1993, we received a number of citizen petitions requesting that FDA make various changes to the Nutrition and Supplement Facts labels. We are addressing a number of issues raised in the following petitions within this proposed rule: (1) The Calorie Control Council submitted a citizen petition on April 13, 1995 (Docket No. FDA-1995-P-0142) requesting that FDA permit the use of the term "polyols" in lieu of sugar alcohols on the Nutrition Facts label (<http://www.regulations.gov/#!docketDetail;D=FDA-1995-P-0142>); (2) the American Cocoa Research Institute submitted a citizen petition on April 4, 1996 (Docket No. FDA-1996-P-0035) recommending the accurate communication of the scientific fact that stearic acid does not affect blood cholesterol (<http://www.regulations.gov/#!docketDetail;D=FDA-1996-P-0035>); (3) Nabisco, Inc. submitted a citizen petition on May 8, 1997 (Docket No. FDA-1997-P-0476) requesting that FDA amend the definition of "total fat" and "saturated fat" in its food labeling regulations to clarify that acetic, propionic, and butyric acids may be excluded when calculating the amount of fat in a food product (<http://www.regulations.gov/#!docketDetail;D=FDA-1997-P-0476>); (4) the Calorie Control Council submitted a citizen petition on February 13, 1998 (Docket No. FDA-1997-P-0232) requesting that the caloric value of soluble fiber be no more than 2 kcal/g (<http://www.regulations.gov/#!docketDetail;D=FDA-1997-P-0232>); (5) the Center for Science in the Public Interest (CSPI) submitted a citizen petition on August 4, 1999 (Docket No. FDA-1999-P-0158) requesting that FDA establish a DV for added sugars and require the amount of added sugar, and the percent DV that represents, to be declared on food labels (<http://www.regulations.gov/#!docketDetail;D=FDA-1999-P-0158>); (6) Protein Technologies International, Inc. submitted a citizen petition on December 21, 2000 (FDA-2000-P-0569) requesting that FDA modify the reference to the method used to calculate protein content (<http://www.regulations.gov/#!docketDetail;D=FDA-2000-P-0569>); (7) the National Starch and

Chemical Company ("National Starch") submitted a citizen petition on July 8, 2004 (Docket No. FDA-2004-P-0094) requesting that dietary fiber content be excluded from the "total carbohydrate" declaration on the Nutrition Facts label (<http://www.regulations.gov/#!docketDetail;D=FDA-2004-P-0094>); (8) the Sugar Association submitted a citizen petition on August 15, 2005 (Docket No. FDA-2005-P-0373) requesting, in part, that FDA amend regulations related to the labeling of sugar and alternative sweeteners (<http://www.regulations.gov/#!docketDetail;D=FDA-2005-P-0373>); (9) CSPI submitted a citizen petition on November 8, 2005 (Docket No. FDA-2005-P-0196) requesting, in part, that FDA lower the DV for sodium from 2,400 to 1,500 mg/day (<http://www.regulations.gov/#!docketDetail;D=FDA-2005-P-0196>); (10) an individual submitted a citizen petition on May 25, 2005 (Docket No. FDA-2005-P-0126) requesting that FDA preclude the declaration of  $\beta$ -carotene in supplements as vitamin A (<http://www.regulations.gov/#!docketDetail;D=FDA-2005-P-0126>); (11) an individual submitted a citizen petition on January 17, 2007 (Docket No. FDA-2007-P-0404) requesting that FDA amend the definition of trans fat in its food labeling regulations to express the value of "zero" for trans fat when there are "absolutely no trans fats at all" and require the use of a symbol (e.g., "~") to indicate when there is "more than zero but less than 0.5 grams (g) of trans fat per tablespoon" (<http://www.regulations.gov/#!docketDetail;D=FDA-2007-P-0404>); and (12) CSPI submitted a citizen petition on February 13, 2013 (Docket No. FDA-2013-P-0217) requesting, in part, that FDA revise the "Sugars" line on the Nutrition Facts label to address "added sugars" (<http://www.regulations.gov/#!docketDetail;D=FDA-2013-P-0217>).

We address the specific requests identified previously for each citizen petition related to the labeling of conventional foods and dietary supplements in the appropriate sections in this

document. Requests in these citizen petitions that are unrelated to the content of the Nutrition Facts label are outside of the scope of this rulemaking and we will address those requests separately from this rulemaking.

#### 6. Advance Notices of Proposed Rulemaking (ANPRMs)

We also published three ANPRMs seeking public comment on issues relevant to updating the Nutrition Facts label.

a. ANPRM on Trans Fat--In the Federal Register of July 11, 2003 (68 FR 41507), we published an ANPRM (the 2003 ANPRM) to solicit information and data that potentially could be used to establish new nutrient content claims about trans fatty acids; to establish qualifying criteria for trans fat in nutrient content claims for saturated fatty acids and cholesterol, lean and extra lean claims, and health claims that contain a message about cholesterol-raising lipids; and, in addition, to establish disclosure and disqualifying criteria to help consumers make heart-healthy food choices. We also requested comments on whether we should consider statements about trans fat, either alone or in combination with saturated fat and cholesterol, as a footnote in the Nutrition Facts label or as a disclosure statement in conjunction with claims to enhance consumer understanding about cholesterol-raising lipids and how to use the information to make healthy food choices. On March 1, 2004 (69 FR 9559), we reopened the comment period for the 2003 ANPRM to receive comments that considered the information in the IOM Labeling Report (Ref. 25) published in the interim that addressed the labeling of trans fat. On April 19, 2004 (69 FR 20838), we extended the comment period for the 2003 ANPRM to receive comments that considered the information in the 2004 meeting of the Nutrition Subcommittee of the Food Advisory Committee (Ref. 46), which addressed whether the available scientific evidence

supported listing the percent DV for saturated fat and trans fat together or separately on the Nutrition Facts label and what the maximal daily intake of trans fat may be.

In response to the 2003 ANPRM , we received about 120 comments. We consider the comments related to determining a DV for trans fat in section II.B.3. (see also accompanying Ref. 47). Other issues raised by comments that are unrelated to the DV for trans fat will be addressed in a separate rulemaking at a future time.

b. ANPRM on Prominence of Calories--In the Federal Register of April 4, 2005 (70 FR 17008), we published an ANPRM on the prominence of calories on the food label (the 2005 ANPRM). The 2005 ANPRM was issued in response to recommendations from the Obesity Working Group created by the Commissioner of Food and Drugs to develop an action plan to address the growing incidence of obesity in the United States. The 2005 ANPRM, in part, requested comments on whether giving more prominence to the declaration of calories per serving would increase consumer awareness of the caloric content of the packaged food. We also sought comment on whether providing a percent DV for total calories would help consumers understand the caloric content of the packaged food in the context of a 2,000 calorie diet. In addition, we also requested comments on questions concerning the declaration of "Calories from fat" (70 FR 17008 at 17010).

We received about 400 comments to the 2005 ANPRM, each containing one or more issues, from industry, trade associations, consumer groups, individual consumers, government, and academia. We consider the comments in sections II.A. and II.M. (see also accompanying Ref. 47).

c. ANPRM on Food Labeling: Revision of Reference Values and Mandatory Nutrients-- In the Federal Register of November 2, 2007 (72 FR 62149), we published an ANPRM regarding

the revision of reference values and mandatory nutrients (the 2007 ANPRM). The 2007 ANPRM requested comment on various aspects of nutrition labeling, including what new reference values we should use to calculate the percent DV in the Nutrition Facts and Supplement Facts labels and what factors we should consider in establishing such new reference values. In addition, we requested comments on whether we should require that certain nutrients be added or removed from the Nutrition Facts and Supplement Facts labels

In response to the 2007 ANPRM, we received about 820 comments, from industry, trade associations, consumer groups, individual consumers, government, and academia. We consider these comments in each of the relevant individual nutrient sections in this document (see also accompanying Ref. 47).

#### 7. Impact on Other Regulations

We recognize that changes to the list of nutrients declared on the Nutrition Facts label or the RDIs or DRVs of nutrients will likely affect other FDA regulations, including certain labeling requirements for foods in 21 CFR part 101. For example, the DVs are used to determine, in part, whether a food or dietary supplement is eligible to bear nutrient content claims or health claims (see for example §§ 101.14, 101.54, 101.76, 101.78, and 101.79). In addition, our fortification policy refers to RDIs and certain DRVs that are specified in § 101.9 in describing principles for the rational addition of nutrients to foods (§ 104.20 (21 CFR 104.20)). We plan to evaluate the impact of the proposed changes to the Nutrition Facts and Supplement Facts labels, if finalized, on other FDA regulations. We intend to address, as appropriate, the impact on other FDA regulations in future separate rulemakings. Thus, issues related to nutrient content claims and health claims are outside the scope of this rulemaking.

#### C. Factors for Mandatory or Voluntary Declaration of Non-Statutory Nutrients

Under section 403(q)(1)(C) and (D) of the FD&C Act, nutrition information in food labeling must include the total number of calories, derived from any source and derived from the total fat, and the amounts of total fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, dietary fiber, and total protein. For purposes of this proposed rule, we consider the nutrients that are explicitly required by the FD&C Act to be declared on the Nutrition Facts label as "statutorily required nutrients." Section 403(q)(2)(B) of the FD&C Act permits the Secretary, and by delegation, FDA, to remove a statutorily required nutrients from the label or labeling of food, by regulation, if the Secretary determines the information related to that nutrient is not necessary to assist consumers in maintaining healthy dietary practices. FDA regulations require the declaration of the following statutorily required nutrients: Total calories, calories from fat, total fat, saturated fat, cholesterol, sodium, total carbohydrates, sugars, dietary fiber, and total protein (See Ref. 1 for information on regulatory history). As part of the effort to update the Nutrition Facts label, we reconsidered the declaration of these statutorily required nutrients. Our considerations and tentative conclusions on these nutrients are presented within the discussion of individual nutrients in section II.

Section 403(q)(2)(A) of the FD&C Act provides that the Secretary (and by delegation FDA) may, by regulation, require other nutrients to be declared if the Secretary determines that a nutrient will provide information regarding the nutritional value of such food that will assist consumers in maintaining healthy dietary practices. For purposes of this proposed rule, we consider such nutrients that are not statutorily required but subject to our discretion under section 403(q)(2)(A) of the FD&C Act, as "non-statutory nutrients" to distinguish such nutrients from those expressly required by the statute. In the 1993 nutrient content final rule (58 FR 2079), we considered the existence of a quantitative intake recommendation highlighted in U. S. consensus

reports and the public health significance of the nutrient in exercising our discretion to determine which non-statutory nutrients to require or permit on the Nutrition Facts label. Based on these considerations, with respect to non-statutory nutrients, we (1) required the declaration of certain essential vitamins and minerals for which an RDI was established and that were determined to have public health significance (i.e., vitamins A and C, iron, and calcium); and (2) permitted the declaration of the remaining essential vitamins and minerals for which there was an established RDI or DRV (i.e., vitamin E) or that had public health significance, as well as permitted the declaration of certain subcategories of macronutrients for which a DRV was not established (including monounsaturated fat, polyunsaturated fat, soluble fiber, insoluble fiber, sugar alcohol, and other carbohydrate) (58 FR 2079).

In this section, we describe our current thinking related to considerations used to determine whether a non-statutory nutrient should be required or permitted to be declared on the Nutrition Facts label. Applying this current thinking, in section II, we are proposing the mandatory declaration of certain non-statutory nutrients, voluntary declaration of others, and proposing to remove the mandatory declaration of another nutrient. For purposes of this proposed rule, we use the term "nutrient" to refer to substances that are currently included or that we are considering for inclusion on the Nutrition Facts label, including carbohydrate, fat, and protein and their subcomponents (e.g., added sugars, sugar alcohols, saturated fat), micronutrients (vitamins and minerals), and to calories, including calories from fat.

#### 1. Factors Considered

We updated the information that we consider for determining whether the declaration of a non-statutory nutrient should be mandatory or voluntary. This update responds to several developments. Since the 1993 nutrient content final rule was published, (1) new scientific data

have provided additional evidence of the role of certain nutrients in chronic disease risk, health-related conditions, or health-related physiological endpoints and, in some cases, based on the review of this evidence, DRIs are now available from the IOM that can be used as quantitative intake recommendations (i.e., RDA and AI), as well as for assessing the inadequacy and adequacy of essential vitamins and minerals in the U. S. population (i.e., EAR and AI); (2) the rates of certain diseases or health-related conditions have either changed or remained high; and (3) the process for evaluating the relationship between a nutrient and chronic disease risk, a health-related condition, or a health-related physiological endpoint has been refined based on the use of systematic evidence-based reviews for a number of nutrients (e.g., 2010 DGA, FDA health claims).

We continue to be mindful of past factors we considered as part of our deliberations related to the Nutrition Facts label, such as the number of nutrients that could be listed in nutrition labeling, that some individuals could interpret a long list of nutrients as implying that a food has greater nutritional significance than is the case, and that there is limited space for nutrition information on the label (55 FR 29487 at 29493; July 19 1990).

To help us determine whether a non-statutory nutrient should be a required or permitted declaration, we are considering the same general types of information used in 1993 when the nutrient content final rule was published: (1) Existence of quantitative intake recommendations; and (2) public health significance. We discuss each of these factors in greater detail in this document.

a. Quantitative Intake Recommendations--Quantitative intake recommendations are reference intake levels provided in consensus reports that can be used to set a DRV or RDI. We expect these consensus reports to be published for the purpose of setting quantitative intake

recommendations (e.g., the IOM DRI reports). If DRIs are not available for nutrients, other than essential vitamins and minerals, then we consider science-based recommendations from other U. S. consensus reports or the DGA policy reports. Such recommendations may be identified as a conclusion, key recommendation, or reported in the executive summary of the consensus report.

b. Public Health Significance--For the purposes of nutrition labeling of foods and dietary supplements, we consider public health significance to refer to two elements. First we consider whether there is evidence of a relationship between the nutrient and a chronic disease, health-related condition, or health-related physiological endpoint. This can be demonstrated either by well-established evidence or, for essential vitamins and minerals, recommendations regarding the health consequences of inadequacy of the nutrient. Second we consider whether there is evidence of a problem related to health in the general U. S. population. This needs to be demonstrated by both evidence of a problem with the intake of the nutrient in the general U. S. population and evidence of the prevalence of the chronic disease, health-related condition, or health-related physiological endpoint that is linked to that nutrient in the general U. S. population. We consider public health significance to refer to the following: (1) Existence of "well-established" scientific evidence from U. S. consensus reports that there is a relationship between a nutrient and chronic disease risk, a health-related condition, or a health-related physiological endpoint and where the intake of such nutrient is of general importance in the general U. S. population, e.g., where intakes are generally too low or too high among the U. S. population. U. S. consensus reports are those reports that provide consensus conclusions or recommendations by a group of experts as requested by U. S. Government Agencies (e.g., IOM reports, the DGAs, National Institutes of Health (NIH) consensus reports). We generally consider scientific evidence to be "well-established" when such consensus reports have determined the evidence to be "conclusive,"

"documented," or "strong." Evidence that meets the significant scientific agreement standard in section 403(r)(3)(B)(i) of the FD&C Act in support of those nutrients and disease or health-related conditions for which we have authorized a health claim would be considered "well-established" evidence for the purposes of what public health significance refers to in this proposed rule; or (2) nutrients for which there are DRIs set by the IOM ( i.e., RDA or AI) that are based on chronic disease risk (e.g., osteoporosis), a health-related condition (e.g., blood pressure) or a nutrient deficiency with clinical significance (e.g., low iron storage leading to iron deficiency anemia) for which inadequate intakes of these nutrients are likely to have important clinical consequences. The nutrients for which this may occur are essential vitamins and minerals; and (3) for all nutrients, there is evidence of inadequate or excess intake of the nutrient based on national nutritional survey data or U. S. consensus reports, and that a substantial prevalence exists in the general U. S. population of the chronic disease, health-related condition, or health-related physiological endpoint that was linked to the particular nutrient (e.g., soluble fiber and coronary heart disease (CHD) risk, calcium and risk of osteoporosis). Because we remain concerned about the large number of nutrients that could be listed as mandatory or voluntary, for essential vitamins and minerals, we are proposing for mandatory declaration, those for which inadequacy has the greatest impact on public health because of their association with a risk of chronic disease, a health-related condition, or a nutrient deficiency with clinical significance (e.g., iron deficiency anemia).

The methods used in the evaluation of public health significance of essential vitamins and minerals are discussed in greater detail in section II.H. and the accompanying reference document (Ref. 48).

## 2. Approach for Mandatory Declaration

In general, we continue to consider mandatory declaration appropriate when there is public health significance and a quantitative intake recommendation that can be used for setting a DV (DRV or RDI). However, we have also considered mandatory declaration based, in part, on evidence highlighting the role of a nutrient in chronic disease risk. For example, in 2003, we published a final rule requiring trans fat declaration on the Nutrition Facts label (68 FR 41434). We considered data and information related to the risk of coronary heart disease from consumption of trans fat. In addition, we considered the public health significance of trans fat intake based on consensus reports and federal policy statements.

Information related to nutrient intake and its effect on health is not static. Recommendations from various scientific bodies of the U. S. Government that are responsible for public health protection or research directly relating to human nutrition may change or evolve over time. We include, as part of our review of nutrient information in this proposed rule, the current recommendations from such scientific bodies. In section D.3, we specifically consider recommendations from the 2010 DGA related to the intake of added sugars in the diet and the role of such information in assisting consumers to maintain healthy dietary practices. Our review is not based on the factors we have traditionally considered for mandatory declaration that are related to chronic disease, health-related condition, or health-related physiological endpoint linked to the particular nutrient. Instead, our review is based on the need for nutrient information for consumers to implement key dietary recommendations to assist consumers to maintain healthy dietary practices and the need for consumers to be able to readily observe and comprehend the information and to understand its relative significance in the context of a total daily diet.

### 3. Approach for Voluntary Declaration

For nutrients that are not essential vitamins and minerals (e.g., fluoride, soluble and insoluble fiber, monounsaturated fatty acids and polyunsaturated fatty acids), we consider voluntary declaration to be appropriate when the nutrient either has a quantitative intake recommendation but does not have public health significance, or does not have a quantitative intake recommendation available for setting a DRV but has public health significance. In addition, we consider that voluntary declaration should be permitted for essential vitamins or minerals that we determine do not fit within our considerations for mandatory declaration, but that have an RDI.

We invite comment on the factors for considering mandatory and voluntary declaration of non-statutory nutrients.

## II. The Proposed Rule

In this proposed rule, we address issues related to the information declared on the Nutrition Facts label, i.e., declaration of nutrients, definitions, analytical methods, RDIs and DRVs, format, and compliance with declared values. Sections II.A. through II.E. discuss issues related to calories and macronutrients (including fat, fatty acids, cholesterol, carbohydrates, sugars, fiber, and protein), whereas sections II.F. through II.J. discuss issues related to vitamins and minerals, and sections II.K. and II.L. discuss nutrition labeling requirements applicable to certain population subgroups and dietary supplements, respectively. Section II.M. covers issues related to the format of the Nutrition Facts label, followed by section II.N., which focuses on provisions related to compliance and verification. Finally, section II.O. describes technical amendments to existing provisions in § 101.9.

As discussed in this document, our evaluation of these issues was informed by current scientific evidence, dietary recommendations, and conclusions of current consensus reports. We took into account any related requests from petitioners and public comments.

### A. Calories

Section 403(q)(1)(C) of the FD&C Act requires the declaration of the total number of calories derived from any source. Correspondingly, FDA regulations require the total caloric content of a food to be declared on the Nutrition Facts label (§ 101.9(c)(1)). We are not proposing to modify the requirement to declare total calories. However, we are reconsidering a number of other requirements related to the declaration of information about calories. The requirements related to "Calories from fat," "Calories from saturated fat," the 2,000 reference calorie intake level, and a percent DV for calories are discussed in section II.A., whereas requirements related to prominence of the calorie declaration and the footnote statement and table of DVs for 2,000 and 2,500 calorie diets are discussed in section II.M.

#### 1. Calories From Fat

The declaration of "Calories from fat" is mandatory (§ 101.9(c)(1)(ii)). Section 403(q)(1)(C)(ii) of the FD&C Act requires total calories from fat to be declared on the label or labeling of food. Section 403(q)(2)(B) of the FD&C Act provides the Secretary of Health and Human Services (and by delegation, FDA) with discretion to remove the requirement by regulation if the Secretary determines that it is not necessary to assist consumers in maintaining healthy dietary practices. We reviewed current scientific evidence and recommendations in current consensus reports in determining whether information on calories from fat is necessary to assist consumers in maintaining healthy dietary practices. We also considered comments (Ref. 47) to the 2005 and 2007 ANPRMs, in which we requested comment on various questions

related to "Calories from fat" declared on the Nutrition Facts label. Unlike dietary recommendations that we relied on during the 1993 rulemaking, current dietary recommendations no longer emphasize total fat. Certain fatty acids are understood to be beneficial, while others are understood to have negative health effects, particularly related to cardiovascular disease (Refs. 6, 36, and 49). Accordingly, the 2005 DGA shifted its focus from total fat reduction to reduction in certain types of fatty acids and their influence on the risk of cardiovascular disease (Ref. 36). The 2002 IOM Macronutrient Report (Ref. 49) set an AMDR for total fat at 20 to 35 percent of calories, recognizing that there were some benefits to consuming moderate amounts of fat (Ref. 49). The 2002 IOM Macronutrient Report and the 2010 DGA (Refs. 6 and 49) concluded that the type of fat consumed was more relevant in reducing the risk of CHD than overall total fat intake.

Based on these dietary recommendations and consensus reports that emphasize intake of total calories and the type of fat consumed, as well as comments to the 2005 and 2007 ANPRMs that supported eliminating the declaration of "Calories from fat" in order to place greater emphasis on total calories (Ref. 47), we tentatively conclude that declaration of "Calories from fat" is not necessary to assist consumers in maintaining healthy dietary practices.

Therefore, we are proposing to no longer require, and to not allow voluntarily, the declaration of "Calories from fat" on the Nutrition Facts label. While eliminating the declaration of "Calories from fat" may appear to be a loss of information on the amount of fat being consumed, as some comments suggested, the amount of fat being consumed can still be obtained from the total fat declaration elsewhere on the Nutrition Facts label, and consumers can still use the percent DV for total fat to put fat content in the context of a total daily diet, compare products, and plan diets. Therefore, we are proposing to remove current § 101.9(c)(1)(ii) to remove the requirement for

declaration of calories from fat (and redesignate § 101.9(c)(1)(iii) as proposed § 101.9(c)(1)(ii)). We invite comment on the tentative conclusion to no longer require, and to not allow voluntarily the declaration of "Calories from fat" on the Nutrition Facts label.

## 2. Calories From Saturated Fat

The declaration of "Calories from saturated fat" is voluntary (§ 101.9(c)(1)(iii)). The 2010 DGA continues to recommend that Americans should consume less than 10 percent of calories from saturated fat (Ref. 6). Saturated fat is known to increase the risk of cardiovascular disease and, unlike "Calories from fat," which could include calories attributable to fatty acids that decrease or increase the risk of certain diseases, "Calories from saturated fat" would provide information about calories from a source known to increase disease risk (Ref. 49). We considered the recommendations in current consensus reports as well as the comments (Ref. 47) received in response to the 2007 ANPRM requesting comment on whether the declaration of "Calories from saturated fat" should continue to be voluntary or whether it should be mandatory.

Based on the recommendations in current consensus reports and supported by many comments, we tentatively conclude that mandatory declaration of "Calories from saturated fat" is not necessary because the amount of saturated fat being consumed can still be obtained from the total saturated fat declaration elsewhere on the Nutrition Facts label. Additionally, as with total fat, consumers can still use the percent DV for saturated fat to put saturated fat content in the context of a total daily diet, compare products, and plan diets. However, because there is strong evidence associating higher intakes of saturated fat with higher low-density lipoprotein (LDL) cholesterol levels, information on "Calories from saturated fat" can assist consumers in maintaining healthy dietary practices. Therefore, we are not proposing to change the current voluntary labeling of "Calories from saturated fat" in the Nutrition Facts label as specified in

§ 101.9(c)(1)(iii). However, considering our proposal to eliminate the declaration of "Calories from fat" on the Nutrition Facts label (see section II.A.1.), we are proposing to revise § 101.9(c)(1)(iii) and (d)(5) to specify that the statement "Calories from saturated fat," when declared, must be indented under the statement of calories. In addition, we are proposing to redesignate § 101.9(c)(1)(iii) as proposed § 101.9(c)(1)(ii).

### 3. Two Thousand Calories as the Reference Caloric Intake Level

Per FDA regulations, a reference calorie intake level of 2,000 calories is used to set DRVs for total fat, saturated fat, total carbohydrate, protein, and dietary fiber (§ 101.9(c)(9)). In addition, we require a footnote on the Nutrition Facts label that states, "Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs," followed by a table with certain DVs based on 2,000 and 2,500 calorie diets (§ 101.9(c)(9)). In reconsidering the 2,000 calories reference intake level, we considered relevant recommendations from the IOM macronutrient report that provided estimated energy requirements (EERs) and the IOM Labeling Report (Refs. 25 and 50). We also considered comments (Ref. 47) received in response to the 2007 ANPRM, in which we asked whether 2,000 calories should continue to be used as the reference calorie intake level and asked questions related to the use of the EERs.

An EER is a DRI set by the IOM for energy intake and is defined as the dietary energy intake that is predicted to maintain energy balance in a healthy adult of defined age, gender, weight, height, and level of physical activity consistent with good health. The IOM set EERs for all life-stage and gender groups and based these EERs on normal weight individuals (i.e., BMI < 25) (Ref. 50). The IOM Labeling Committee considered whether there was a basis to use the EERs for developing a new reference calorie intake level for macronutrients in nutrition labeling.

The IOM Labeling Committee noted that using the EER to derive a reference calorie intake level would require making assumptions about height, weight, and physical activity level.

Furthermore, the equations used to calculate the EERs were based on normal weight individuals; however, the American population has a high prevalence of overweight and obesity. Thus, the IOM Labeling Committee found that the data necessary to use the EER concept as the basis for a reference calorie intake level for nutrition labeling were incomplete and it could not recommend the approach (Ref. 25). The IOM Labeling Committee concluded that retaining the current 2,000 reference calorie intake level would be the best approach as it would provide continuity and would not encourage higher calorie intake and overconsumption of energy (Ref. 25).

We agree with the IOM Labeling Report and comments in response to the 2007 ANPRM (Ref. 47) that the EERs do not provide an appropriate basis for the derivation of a reference calorie intake level for the purpose of nutrition labeling. The EERs are influenced by various parameters such as age, gender, height, weight, and physical activity level (PAL), which makes it challenging to combine the EERs into a single reference calorie intake level applicable to the general population. Further, all of the comments supported the use of the 2,000 calorie reference intake level.

Therefore, we are not proposing any changes to the current use of 2,000 reference calorie intake level as the basis for setting DRVs for total fat, saturated fat, total carbohydrate, dietary fiber, and protein, as specified in § 101.9(c)(9).

#### 4. Percent DV Declaration for Calories

Current regulations do not provide for a DRV for calories. Setting a DRV for calories would necessitate the determination of a quantitative intake recommendation for calories. To determine an appropriate DRV for calories, we reviewed recommendations in current consensus

reports. We also considered comments (Ref. 47) received in response to the 2005 and 2007 ANPRMs, in which we asked whether providing a percent DV disclosure for total calories would assist consumers in understanding the caloric content of the packaged food in the context of a 2,000 calorie diet. The IOM macronutrient report is the most recent consensus report that provides quantitative intake recommendations for calories (Ref. 50), and those quantitative intake recommendations are the EERs. For the same reasons that EERs are not appropriate for setting the reference calorie intake level as described previously, these EERs are not appropriate for setting a DV for calories. First, the EERs do not apply to overweight individuals, and are therefore not applicable to a substantial portion of the general population. Second, combining the EERs into a single, meaningful reference value is challenging because they vary by age, gender, height, weight, and PAL. In addition, DRVs were established for those nutrients that are important in diet and health interrelationships and/or based on caloric intake (55 FR 29476 at 29479; July 19, 1990). Accordingly, most of the DRVs have been based on quantitative intake recommendations associated with chronic disease risk or a health-related condition (e.g., total fat, saturated fat, cholesterol, and dietary fiber). In contrast, the EERs are neither associated with chronic disease risk or a health-related condition, nor are they intended to be treated as a single recommended value that can be applied to the general U. S. population. Thus, we tentatively conclude that there is no appropriate quantitative intake recommendation and we are not aware of any other data or information on which a DRV for calories can be determined. Although a majority of comments to the ANPRMs supported the addition of a percent DV for total calories, we are not persuaded to propose to require or permit such declaration due to the lack of an appropriate quantitative intake recommendation or other data or information on which FDA

could rely to establish a DRV for calories. We invite comment on the tentative conclusion not to establish a DRV for calories and include a percent DV for the declaration of calories.

Therefore, we are not proposing to set a DRV for calories and, as a result, a percent DV declaration for calories would be neither required nor permitted.

## B. Fat

In section II.B., we discuss considerations related to definitions, declaration, and DRVs for total fat, saturated fat, trans fat, monounsaturated fat, and polyunsaturated fat.

### 1. Total Fat

a. Definition--FDA defines "fat, total" or "total fat" in § 101.9(c)(2) as a statement of the number of g of total fat in a serving defined as total lipid fatty acids and expressed as triglycerides.

In 1997, we received a citizen petition from Nabisco, Inc. (Docket No. FDA-1997-P-0476) requesting that FDA amend the definitions of "total fat" and "saturated fat" in its food labeling regulations to clarify that acetic, propionic, and butyric acids may be excluded when calculating the amount of fat in a food product (<http://www.regulations.gov/#!docketDetail;D=FDA-1997-P-0476>). The petitioner's requests related to the definition and labeling of total fat are presented here and the petitioner's requests related to the definition of saturated fat are discussed in section II.B.2.

With respect to total fat, the petitioner requested that we amend § 101.9(c)(2) to read as follows: "Fat, total" or "Total fat": A statement of the number of g of total fat in a serving defined as total lipid fatty acids, excluding acetic (C:2), propionic (C:3), and butyric (C:4) acids and expressed as triglycerides..." The petitioner stated that acetic, propionic, and butyric acids ("the acids"), which have very short two, three, and four carbon chains, respectively, are organic

acids that should not be considered fatty acids for food labeling purposes for the following reasons: (1) The acids are chemically different from fatty acids because they are water soluble; (2) the digestion and absorption of the acids are distinctly different from those of fatty acids; (3) the acids are metabolized differently than fatty acids and are biochemically and physiologically more closely related to carbohydrates than to fat; and (4) the acids do not cause the adverse health effects associated with fat and may even have benefits that make them distinct from fat. The petitioner noted that excluding the acids from the definition of fat would not affect current labeling practices because they are found in such small amounts in the food supply. In addition, the petitioner asserted that analytical methods would not be affected because approved AOAC methods for total fat measurement do not detect the acids.

We disagree with the petitioner that the acids are chemically different from fatty acids because they are water soluble and that insolubility in water is the essential chemical property of a fat. Fatty acids are monocarboxylic acids with chain lengths between 1 and nearly 30 carbon atoms (Ref. 51). The chain length of a fatty acid determines its physical properties (Ref. 51). Short-chain fatty acids are compounds that are soluble in water. As the chain length increases, water-solubility decreases (Ref. 51). Short chain acids such as acetic, propionic, and butyric acids are still considered fatty acids although they are water soluble. Furthermore, the characteristic feature of a fatty acid is a terminal carboxyl group attached to a chain of alkyl groups containing carbon atoms of which these short chain acids are composed (Ref. 52).

We determine the amount of the major macronutrients (carbohydrate, fat, and protein) in a food product by their chemical composition. We tentatively conclude that the petitioner did not provide a scientific basis on which we could rely to propose to exclude acetic, propionic, and butyric acids from the definition of total fat based on differences in chemical composition.

Moreover, the petitioner did not explain why we should define total fat based on physiological differences identified for such fatty acids compared to other fatty acids, even if true, and not retain our current approach to define total fat based on chemical composition. Therefore, we are not proposing any changes to the current definition of "total fat." We request comment on our tentative conclusion that acetic, propionic, and butyric acids should not be excluded from the definition of "total fat."

To clarify what we consider to be a fatty acid, we are proposing to define "fatty acids" in § 101.9(c)(2) as "aliphatic carboxylic acids consisting of a chain of alkyl groups and characterized by a terminal carboxyl group." This definition is consistent with other similar definitions found in nutrition and chemistry references (Refs. 51 to 54). We request comment on the proposed definition of fatty acids.

b. Mandatory Declaration--Section 403(q)(1)(D) of the FD&C Act requires the declaration of the amount of total fat on food labels. Consequently, the Nutrition Facts label includes the mandatory declaration of the gram amount for total fat in § 101.9(c)(2).

The 2010 DGA recognizes that the types of fatty acids consumed are more important in influencing the risk of CVD than the total amount of fat in the diet (Ref. 6). Current dietary recommendations and clinical guidelines encourage replacing saturated and trans fatty acids with beneficial fats, such as polyunsaturated and monounsaturated fatty acids (Refs. 6 and 55). A high intake of most types of saturated fatty acids, trans fatty acids, and cholesterol can increase LDL cholesterol levels, which in turn may increase the risk of CHD (Ref. 49). While there is a significant amount of evidence showing that a diet high in saturated or trans fatty acids may be detrimental to health, there is also evidence that consumption of less than 20 percent of calories from fat can lead to an increased risk of insufficient intake of vitamin E and essential fatty acids

(Ref. 49). In addition, consumption of a low fat diet that is high in carbohydrate can lead to a reduction in high density lipoprotein cholesterol concentration and an increase in blood triglycerides, which can result in an increased risk of CHD (Ref. 49).

We concur with the 2010 DGA that consuming a diet low in saturated fatty acids and cholesterol is more important for reducing CVD risk than consuming a diet low in total fat. This finding is consistent with the conclusions in the IOM Macronutrient Report (Ref. 49), as well as with current practice guidelines such as the National Heart, Lung, and Blood Institute (NHLBI) Third Report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Ref. 55). Total fat is a calorie-yielding macronutrient and an important piece of the macronutrient profile of a food. However, consumption of inadequate amounts of total fat is also associated with an increased risk of impaired growth and consumption of excessive amounts of total fat is associated with an increased risk of chronic diseases, such as CHD and diabetes (Ref. 49). In addition, the IOM noted that high fat diets are usually accompanied by increased intakes of saturated fatty acids which can increase the risk of CHD (Ref. 49). Thus, we tentatively conclude that mandatory declaration of total fat on the Nutrition Facts label continues to be necessary to assist consumers in maintaining healthy dietary practices. Therefore, we are not proposing any changes to the current requirement for mandatory declaration of total fat on the Nutrition Facts label.

c. DRV--The DRV for total fat is 30 percent of calories (65 g/d) (§ 101.9 (c)(9)). In developing the DRIs for various nutrients, the IOM cited a lack of data sufficient to determine a defined level of fat intake at which no risk of inadequacy or prevention of chronic disease occurs, and therefore, decided to establish neither an AI nor an RDA for total fat (Ref. 49). Instead, the IOM established an AMDR for total fat intake of 20 to 35 percent of energy for

adults and an AMDR of 25 to 35 percent of energy for children age 4 to 18 years. The AMDRs are associated with reduced risk of chronic diseases, such as CHD, while providing for adequate intake of essential nutrients. The 2010 DGA acknowledged the IOM's AMDR and noted that total fat intake should fall within the AMDRs set by the IOM (Ref. 6). The IOM Labeling Committee recommended that AMDRs should be the basis for DVs for protein, total carbohydrate, and total fat (72 FR 62149 at 62164). Accordingly, for total fat, the IOM Labeling Committee recommended a population-weighted midpoint of the AMDR since AMDRs vary with age. A population-weighted mid-point of the AMDR for adults, i.e., 20 to 35 percent, yields a DRV of 28 percent or 62 g of total fat. The use of the upper level (35 percent of energy) of the AMDR would increase the DRV from 65 g to 78 g for a 2,000 calorie diet.

Considering the recommendations of the IOM Labeling Committee, we requested comment, in the 2007 ANPRM, on: (1) Whether a population-weighted midpoint of the AMDR (e.g., 28 percent for adults) should be used, as suggested in the IOM Labeling Report and (2) whether the upper level of AMDR of 35 percent (78 g) should be used.

We reviewed the IOM Labeling Committee's recommendations, IOM DRIs, and comments in response to the 2007 ANPRM (Ref. 47). We tentatively conclude that changing the DRV for total fat to the lower end of 20 percent of 2,000 calories would not be appropriate because: (1) It would not be appropriate for children 4 to 18 years of age because it falls below the lower end of the AMDR (i.e., 25 to 35 percent of energy) and (2) scientific evidence supports consumption of greater than 20 percent of total calories from total fat for reduction in risk of chronic diseases, such as CHD and diabetes (Ref. 49).

We also conclude that the upper level of the AMDR of 35 percent of 2,000 calories as the basis for a DRV would provide no meaningful health benefit and that a population-weighted

mid-point of 28 percent of the AMDR (28 percent of calories) as the basis for the DRV is not significantly different from a public health outcome standpoint than the current value of 30 percent of calories. Using the population-weighted AMDR midpoint approach would result in an insignificant reduction from the DRV of 65 g (rounded from 30 percent of a 2,000 calorie diet) to 60 g (rounded from 28 percent of calories), which may imply a greater level of precision in a DRV than is actually true.

Furthermore, the DRV for total fat is linked to the DRVs for total carbohydrate and protein. For reasons discussed in sections II.D. and II.E., we are not proposing to change the DRVs for carbohydrate or protein at this time. Because the DRV for carbohydrate is determined by difference, an increase in the DRV for fat would result in a decrease in the DRV for carbohydrate.

The DRV of 30 percent of calories fits within the AMDR and represents a moderate value that is not close to the upper or lower levels of the AMDR. A majority of comments supported maintaining the current DRV of 30 percent of calories. As noted previously, the DRV for total fat was calculated based on a 2,000 reference calorie intake and the dietary recommendation for fat intake at the time of 30 percent or less of total caloric intake, amounting to 66.7 g of fat, which was rounded down to 65 g. Current dietary recommendations for fat intake provide a range of acceptable intakes (i.e., between 20 and 35 percent of caloric intake) and encompass the 30 percent value that formed the basis for the existing DRV. Therefore, we are not proposing any changes to the current DRV for total fat of 30 percent of calories.

## 2. Saturated Fat

a. Definition--FDA regulations define "Saturated fat" in § 101.9(c)(2)(i) as the sum of all fatty acids containing no double bonds. We received a citizen petition from the American Cocoa

Research Institute on April 3, 1996 (Docket No. FDA-1996-P-0035) requesting that the Agency exclude stearic acid from the definition of saturated fat because the petitioner claimed that stearic acid does not raise LDL-cholesterol levels or the risk of CHD (<http://www.regulations.gov/#!docketDetail;D=FDA-1996-P-0035>). In the 2007 ANPRM, we did not seek comments on the definition of saturated fat, but received a few comments that requested excluding stearic acid from the definition of saturated fat or permitting a separate listing for stearic acid below the line for saturated fat (Ref. 47).

We considered the comments to the 2007 ANPRM and the request by the American Cocoa Research Institute petition, and do not agree that stearic acid should be excluded from the definition of saturated fat. While there is evidence that there are potential differences in the physiological effects of different saturated fatty acids, including on LDL cholesterol levels, the definitions of nutrients for food labeling purposes have traditionally been based on chemical definitions, rather than on individual physiological effects. The definition for saturated fat in § 101.9(c)(2)(i) includes all fatty acids without double bonds and the accepted analytical methods capture all of the saturated fatty acids, including stearic acid. In adopting this definition, we addressed the issue of inclusion/exclusion of individual saturated fatty acids and determined that a chemical definition (which includes all fatty acids containing no double bonds) was the appropriate approach to define saturated fat (58 FR 2079 at 2088). We further note that the 2010 DGA recommendation related to saturated fat intake is based on scientific evidence related to the intake of all saturated fatty acids combined, which includes stearic acid. The DGA recommendation to consume less than 10 percent of calories from saturated fatty acids makes no specific exclusion of stearic acid and, instead, relates to the intake of total saturated fatty acids (Ref. 6). There are no quantitative intake recommendations for stearic acid.

The inclusion of stearic acid in the definition of saturated fat is consistent with our overall approach to rely on chemical definitions of nutrients as the basis for regulatory definitions for food labeling purposes. The American Cocoa Research Institute petition did not provide a basis for why we should deviate from this overall approach to rely on the chemical definition of nutrient as a basis for a regulatory definition. Thus, we are not proposing to exclude stearic acid from the definition of saturated fat.

Finally, we also considered voluntary declaration of stearic acid on the Nutrition Facts label, as recommended by a few comments. The effects of stearic acid on LDL cholesterol levels appear to vary depending on the macronutrient component that is replaced by stearic acid (Ref. 30). Moderate evidence indicates that when stearic acid substitutes for other saturated fatty acids or trans fat, plasma LDL cholesterol levels decrease whereas when it replaces monounsaturated or polyunsaturated fatty acids, LDL cholesterol levels increase (Ref. 30). Considering such scientific data, the 2010 DGAC concluded that the potential effects of changes in dietary intake of stearic acid on the risk of CVD remain unclear. Thus, the evidence for a role of stearic acid in human health (e.g., changes in plasma LDL cholesterol levels) is not well-established. Furthermore, there is no quantitative intake recommendation available for stearic acid. Therefore, we tentatively conclude that the individual declaration of stearic acid is not necessary to assist consumers in maintaining health dietary practices, consistent with the factors we consider, discussed in section I.C., and therefore the declaration would not be permitted on the Nutrition Facts label.

As discussed in section II.B.1., we received a citizen petition from Nabisco, Inc. on May 7, 1997 (Docket No. FDA-1997-P-0476) requesting that FDA amend the definitions of "total fat" and "saturated fat" in its food labeling regulations to exclude acetic, propionic, and butyric acids

(<http://www.regulations.gov/#!docketDetail;D=FDA-1997-P-0476>). With respect to saturated fat, the petition requested that FDA amend § 101.9(c)(2) to read as follows: (i) "Saturated fat," or "Saturated": A statement of the number of g of saturated fat in a serving defined as the sum of all fatty acids, excluding acetic (C:2), propionic (C:3), and butyric (C:4) acids, containing no double bonds." For the same reasons discussed in section II.B.1. regarding total fat, we are not proposing to exclude acetic, propionic, and butyric acids from the definition of saturated fat.

b. Mandatory Declaration--Section 403(q)(1)(D) of the FD&C Act requires the declaration of the amount of saturated fat on food labels. Accordingly, FDA regulations require mandatory declaration of the gram amount for saturated fat (§ 101.9(c)(2)).

Dietary recommendations continue to recognize the well-established relationship between consumption of saturated fat and its effect on blood cholesterol levels (Refs. 6 and 49). In addition, the 2010 DGA provided a quantitative intake recommendation for saturated fat. We are unaware of evidence to support a determination that information relating to saturated fat on the Nutrition Facts label is no longer necessary to assist consumers in maintaining healthy dietary practices. Therefore, we are not proposing to change the requirement for mandatory declaration of saturated fat on the Nutrition Facts label in § 101.9(c)(2)(i).

c. DRV--The DRV for saturated fat is 20 g, which is 10 percent of calories based on a 2,000 reference calorie intake level (§ 101.9(c)(9)). The IOM Labeling Committee recommended that the DV for saturated fatty acids (along with trans fatty acids and cholesterol) should be set at a level that is as low as possible in keeping with an achievable health-promoting diet and consistent with IOM DRIs (Ref. 25). The IOM Labeling Committee suggested that FDA use food composition data, menu modeling, and data from dietary surveys to estimate minimum intakes that are consistent with nutritionally adequate and health-promoting diets for

diverse populations. In the 2007 ANPRM, we asked for public comment on (1) whether the current DRV for saturated fat of 20 g should be retained and (2) whether food composition data, menu modeling, and data from dietary surveys should be used to establish a DRV for saturated fat that is as low as possible while consuming a nutritionally adequate diet. We received several comments in response to these questions (Ref. 47).

Current consensus reports that reviewed scientific evidence related to saturated fatty acid intake continue to recommend saturated fat intakes of no more than 10 percent of calories, based on risk of CVD. Specifically, the IOM DRIs recommended that intakes of these fats should be as low as possible while consuming a nutritionally adequate diet (Ref. 49). In addition, confirming the relationship between high intakes of saturated fatty acids and increased risk of unhealthy blood lipid levels and CHD, the 2010 DGA reaffirmed the recommendation to reduce saturated fatty acid intake to less than 10 percent of calories and noted that lowering the intake even more, to 7 percent of calories, can further reduce the risk of CVD (Ref. 6). The 2002 report from the National Cholesterol Education Program of the NIH National Heart, Lung, and Blood Institute established saturated fat intakes of no more than 10 percent of calories as an optimal intake level for reduction of CHD risk while also establishing intakes of no more than 7 percent of calories as a therapeutic intake level for treating CHD (Ref. 55). Although some comments suggested reducing the DRV to 15 g and to lower the DRV to 7 percent of calories, we are not persuaded to do so because the current saturated fatty acid recommendation of less than 10 percent of calories is still appropriate for the general U. S. population and that the existing DRV of 20 g continues to conform to current dietary recommendations as a maximum intake level that covers the general U. S. population.

We do not consider the use of food composition data, menu modeling, or dietary survey data as a suitable approach to determine DRVs. We note that the majority of comments opposed the use of such alternative methods to determine the DRV for saturated fat.

We established the current DRVs based on quantitative intake recommendations and underlying science on the association between increased intakes and either reduced risk of chronic disease (e.g., dietary fiber and CHD) or increased risk of chronic disease (e.g., saturated fat and CHD). The approach to determine DRVs using food composition data, menu modeling, or dietary surveys has a number of deficiencies. Menu modeling is an approach, based on available foods in the marketplace, to design a set of food items for meals, which will meet certain nutrient or food intake pattern recommendations (Ref. 56). Menu modeling, by its very nature, would not permit the selection of DRVs that are based on scientific evidence related to actual public health outcomes. Furthermore, menu modeling permits the creation of model menus that may be able to meet certain nutrient thresholds through the inclusion of foods that are not representative of the type or quantity of foods eaten in the U. S. population or any specific population and, thus, may result in nutrient intake levels that do not reflect typical diets and, as such, may be unachievable or unreasonable. The use of menu modeling can be appropriate in other circumstances, such as the use of modeling to determine scenarios of highest possible nutrient intake levels or potential nutrient profiles of diets. Thus, food composition data and related models can help provide useful information about consumption trends and the general nutrient content of the food supply and can serve as an additional consideration in choosing a reference point for daily intake that is realistically achievable and practical in light of the current food supply and consumption patterns. However, these data cannot form the primary scientific bases for selecting DRVs. Another challenge with the use of the menu modeling approach is that

numerous and rapid changes to food formulations can make it difficult for food composition databases to provide current and accurate estimates of nutrient intakes. Based on these inherent limitations of menu modeling and the data sources used, we tentatively conclude that the menu modeling approach, as recommended in the IOM Labeling Report, is an unsuitable method for determining DRVs (or RDIs). Instead, we intend to continue using science-based recommendations to set DRVs and RDIs. In the case of saturated fat, as explained previously, the existing scientific evidence does not support a change to the current 20 g DRV. Therefore, we are not proposing any changes to the current DRV of 20 g for saturated fat as specified in § 101.9(c)(9).

### 3. Trans Fat

a. Definition--FDA defines "Trans fat" or "Trans" in § 101.9(c)(2)(ii) as the sum of all unsaturated fatty acids that contain one or more isolated (i.e., non-conjugated) double bonds in a trans configuration. In the 2007 ANPRM, we did not seek public comment on the definition of trans fat. However, we received a comment recommending the exclusion of a specific trans fat isomer, vaccenic acid (18:1 t11) from the definition of trans fat because, according to the comment, unlike other trans fat isomers, vaccenic acid may not have adverse health effects. As discussed in the preamble to the final rule regarding trans fat labeling (68 FR 41434 at 41461), we defined trans fatty acids by their chemical structure, not their physiological effects or functional attributes. While the comment provided us with some preliminary observational data suggesting that trans fat from ruminant sources, such as vaccenic acid, may not have the same effects on CHD risk as trans fat from industrial sources, such as partially hydrogenated oils, we do not agree that potential differences in physiological effects should be the basis for determining the specific isomers to be included in a regulatory definition of trans fat. The

definition for trans fat is its chemical definition which captures all trans fat isomers that have isolated bonds and, thus, vaccenic acid would be measured by the analytical method used to determine trans fat content of foods. This chemical definition is consistent with how polyunsaturated fat is defined as cis, cis-methylene-interrupted (§ 101.9(c)(2)(ii)). Accordingly, we are not proposing to change the definition of trans fat in § 101.9(c)(2)(ii).

b. Mandatory Declaration--FDA regulations require the declaration of trans fat on the Nutrition Facts label (§ 101.9(c)(2)(ii)). Dietary recommendations continue to recognize the well-established relationship between consumption of trans fat and its effect on blood cholesterol levels (Ref. 6). Furthermore, under section 403(r)(3)(C) of the FD&C Act, we did not object to a 2006 Food and Drug Administration Modernization Act of 1997 (FDAMA) notification for the health claim "Diets low in saturated fat and cholesterol, and as low as possible in trans fat, may reduce the risk of heart disease," based on statements made in the 2005 DGA (Ref. 57). As such, because of its role in chronic disease, trans fat continues to be a nutrient with public health significance. We are unaware of evidence to support a determination that information relating to trans fat on the Nutrition Facts label is not necessary to assist consumers in maintaining healthy dietary practices. We tentatively conclude that information on the amount of trans fat in food products allows consumers to reduce their intake of trans fat, and thus, reduce the risk of CHD. Therefore, we are not proposing any changes to the requirement for mandatory declaration of trans fat on the Nutrition Facts label in § 101.9(c)(2)(ii). However the Agency recently published a tentative determination that partially hydrogenated oils, the source of industrially produced trans fat, may not be generally recognized as safe (78 FR 67169; November 8, 2013). We request comment on whether mandatory labeling of trans fat would still be necessary if this determination is finalized.

Per § 101.9(c)(2)(ii), if a food contains less than 0.5 g of trans fat per serving, the content, when declared, is to be expressed as zero. We received a citizen petition from an individual on January 17, 2007 (Docket No. FDA-2007-P-0404) which requested that FDA amend the definition of trans fat in its food labeling regulations to express the value of "zero" for trans fat only when there are "absolutely no trans fats at all" and require the use of a symbol (e.g., "~") to indicate when there is "more than zero but less than 0.5g of trans fat per tablespoon" (<http://www.regulations.gov/#!docketDetail;D=FDA-2007-P-0404>). The petition claimed that the declaration of zero trans fats on the label is misleading to consumers because it does not denote the absence of trans fat (as "zero" is defined in Webster's Dictionary) and that people will consume a food incorrectly thinking that it has zero amount of trans fat. The petition stated that, because trans fat is associated with negative effects on heart health, this situation could be detrimental to people's health.

Validated analytical methodologies that provide sensitive and reliable estimates of trans fatty acids in all foods at levels below 0.5 g per serving are currently not available. For most nutrients declared on the nutrition label, the maximum amount permitted for a declaration of a zero value is governed by the limitations associated with analytical methods available to determine the content of a nutrient in a food. The analytical methods used to determine nutrient content for purposes of compliance are discussed in more depth in section II.N. The petition did not provide any information on alternative analytical methodologies that are more sensitive and reliable nor did the petition provide any evidence to support the claim that consumers are misled by the provisions for the declaration of zero trans fat. Thus, we are not proposing any changes to the requirement for the declaration of zero when trans fat content is less than 0.5 g per serving.

c. DRV--FDA regulations do not provide a DRV for trans fat. At the time of the issuance of the trans fat final rule, we concurrently issued the 2003 ANPRM in the same issue of the Federal Register (68 FR 41507) to solicit information and data on several trans fat labeling issues. In the 2007 ANPRM, we again requested comments on various issues related to the DV for trans fat, including the use of food composition data, menu modeling and data from dietary surveys, and a potential joint percent DV for trans fat and saturated fat. We received several comments in response to the 2007 ANPRM. We considered the recommendations in the IOM Labeling Report, available scientific evidence, and comments (Ref. 47) received in response to both the 2003 and 2007 ANPRMs.

i. Use of food composition data, menu modeling, and dietary surveys. FDA considered the approach recommended in the IOM Labeling Report to use food composition data, menu modeling, and dietary survey data to estimate a minimum trans fat intake within a nutritionally adequate diet.

As explained previously (see section II.B.2.c.), we do not consider food composition data, menu modeling, or dietary survey data suitable for determining DRVs. Furthermore, such an approach is not linked to a health outcome, which we have traditionally used as a basis for determining DRVs. As described in the IOM macronutrient DRI report (Ref. 49), the IOM reviewed the evidence for trans fat and was not able to set a UL for trans fat, which indicates that there is insufficient scientific evidence from which to determine a specific level of trans fat intake that would likely pose no risk of adverse health effects. We continue to adhere to the approach of determining DRVs for a nutrient based on the nutrient's association with specific health outcomes (e.g., LDL cholesterol levels).

As an additional consideration, even if we were to use the menu modeling approach, it would be difficult to apply such an approach for trans fat. Current estimates of trans fat content in food composition databases are not comprehensive and do not include trans fat content for all foods. The levels of trans fat in foods have changed since the publication of the 2003 trans fat final rule, in part due to reformulation of foods (Ref. 58) . The numerous and rapid changes to food formulations can make it difficult for food composition databases to provide current and accurate estimates of the usual intake of trans fat.

Therefore, we tentatively conclude that the menu modeling approach, as recommended in the IOM Labeling Report, is an unsuitable method for determining an appropriate DRV for trans fat.

ii. Determining a DRV. The IOM did not set a UL for trans fat in the DRI macronutrient report. The IOM noted that any increase in trans fat intake increases CHD risk but because trans fats are unavoidable in ordinary diets, consuming zero percent of calories would require significant changes in dietary intake patterns that may introduce undesirable effects and unknown and unquantifiable health risks (Ref. 49). The 2005 and 2010 DGA and the FDA Food Advisory Committee (Refs. 6 and 36) likewise could not set a definitive quantitative intake recommendation for trans fat. Comments generally supported a single trans fat DRV and a single percent DV, but noted that such levels are not possible based on existing science. Although some comments supported a joint percent DV declaration for saturated and trans fat combined, the majority of comments opposed it due in large part to the chemical and physiological differences between these fats. We will consider determining a DRV for trans fat, if and when scientific evidence and relevant dietary recommendations become available. At that time, we will also consider whether a single DRV specific to trans fat or a provision for joint DV

declaration for trans fat and saturated fat are appropriate. Thus, we tentatively conclude that there is no basis for setting a DRV for trans fat and, accordingly, we are not proposing a DRV for trans fat, a joint DRV declaration or joint percent DV declaration.

#### 4. Polyunsaturated Fat

Polyunsaturated fats represent two general categories: n-6 and n-3 polyunsaturated fatty acids. The most common n-6 and n-3 polyunsaturated fatty acid in food is linoleic acid and  $\alpha$ -linolenic acid, respectively. Other n-3 fatty acids found in foods, particularly in fish, are the long chain fatty acids, eicosapentaeneic acid (EPA) and docosahexaenoic acid (DHA).

a. Voluntary Declaration--FDA regulations permit, but do not require, the declaration of polyunsaturated fat (defined as cis, cis-methylene-interrupted polyunsaturated fatty acids) on the Nutrition Facts label (§ 101.9(c)(2)(iii)).

To determine whether any changes are needed to the current provision for voluntary declaration, we considered recommendations of current U. S. consensus reports as well as comments received (Ref. 47) in response to the 2007 ANPRM, in which we requested comment on whether declaration of polyunsaturated fat should continue to be voluntary or made mandatory. Current dietary recommendations advise consumers to increase intakes of polyunsaturated fatty acids to replace saturated fatty acids in their diets (Ref. 6). The 2010 DGA recommends limiting the consumption of saturated fatty acids accompanied with replacing them with polyunsaturated and monounsaturated fatty acids (Ref. 6). However, as discussed in this document, the IOM did not set DRIs for total polyunsaturated fatty acids, but rather provided AIs and AMDRs each for two specific fatty acids, linoleic acid (an n-6 polyunsaturated fatty acid) and  $\alpha$ -linolenic acid (an n-3 polyunsaturated fatty acid) based on median intakes of each fatty acid using NHANES data (Ref. 49).

We acknowledge that certain polyunsaturated fatty acids are essential and understand the interest expressed by some comments that there is a need to provide information on beneficial fats. However, the essentiality of a nutrient is not a factor considered for the mandatory or voluntary labeling of non-statutory nutrients, other than essential vitamins and minerals (see section I.C). Although certain polyunsaturated fatty acids are essential, an essential fatty acid deficiency is basically nonexistent in the United States and, therefore, is not of public health significance (Ref. 49).

A quantitative intake recommendation is not available from relevant U. S. consensus reports (see discussion in this document), but there is well-established evidence to indicate that replacing saturated fatty acids with polyunsaturated and monounsaturated fatty acids reduces blood LDL cholesterol levels and, therefore, the risk of CVD (Ref. 30). The prevalence of CVD in the U. S. population is substantial (Ref. 30). We are not proposing any changes to the requirement for mandatory declaration of saturated fat (see section II.B.2.). Because polyunsaturated fat has public health significance when it replaces saturated fat, consistent with the factors for voluntary declaration discussed in section I.C., we are proposing to continue to permit voluntary declaration of polyunsaturated fat, as provided in § 101.9(c)(2)(iii). We request comment about whether there is an appropriate alternative analysis to the application of the factors in section I.C. regarding the voluntary declaration of polyunsaturated fat.

b. DRV--FDA regulations do not provide a DRV for polyunsaturated fat. The IOM did not set a DRI or AMDR for polyunsaturated fat, but provided AIs and AMDRs for two specific essential fatty acids, linoleic acid (an  $n-6$  polyunsaturated fatty acid) and  $\alpha$ -linolenic acid (an  $n-3$  polyunsaturated fatty acid) based on median intakes of each fatty acid using NHANES data (Ref. 49). The AIs for linoleic acid and  $\alpha$ -linolenic acid are 17 and 1.6 micrograms (mcg)/d,

respectively. The AMDRs for linoleic acid and  $\alpha$ -linoleic acid are 5 to 10 percent of calories and 0.6 to 1.2 percent of calories, respectively. In the 2007 ANPRM, we asked: (1) Whether a DRV for total polyunsaturated fat should be derived based upon AIs for linoleic acid plus  $\alpha$ -linolenic acid; and (2) whether a DRV for total polyunsaturated fat should be established using the AMDRs for  $n$ -6 and  $n$ -3 polyunsaturated fatty acids and, if so, should a midpoint be used. We received comments in response to these questions (Ref. 47).

We are not able to set an appropriate DRV for polyunsaturated fat at this time given the lack of established DRIs for total polyunsaturated fatty acids. We do not consider that the AMDRs or AIs for linoleic acid and  $\alpha$ -linolenic acid provide a sufficient basis on which a DRV for polyunsaturated fat could be derived. The AIs for linoleic and  $\alpha$ -linolenic acid were set based on U. S. median intake levels because there were insufficient experimental data to set an RDA (Ref. 49). Similarly, the AMDRs for linoleic acid and  $\alpha$ -linolenic acid were based on the percent of calories needed to meet the AI for each fatty acid (lower range) and the percent of calories representing the highest intake level of each fatty acid (upper range). As such, neither of these values provides an adequate basis on which to determine a DRV. For these reasons, we disagree with comments that supported using the sum of AIs or AMDRs to establish a DRV for total polyunsaturated fat.

Therefore, we tentatively conclude that there is no appropriate quantitative intake recommendation to form a basis for setting a DRV for polyunsaturated fat. Accordingly, we are not proposing a DRV for polyunsaturated fat.

c. Declaration of Individual Polyunsaturated Fatty Acids--The declaration of individual polyunsaturated fatty acids on the Nutrition Facts label is not permitted. The IOM did not set DRIs for total  $n$ -6 and  $n$ -3 polyunsaturated fatty acids, but established AIs and AMDRs for two

specific fatty acids, linoleic acid (an  $n-6$  polyunsaturated fatty acid) and  $\alpha$ -linolenic acid (an  $n-3$  polyunsaturated fatty acid) (Ref. 49). The 2007 ANPRM asked for public comment on whether separate DRVs for linoleic acid and  $\alpha$ -linolenic acid should be established and, if so, whether the declaration of these nutrients should be voluntary or made mandatory. We received comments in response to these questions (Ref. 47).

Linoleic and  $\alpha$ -linolenic acids are essential fatty acids that differ physiologically and compete metabolically. Based on a review of relevant scientific research, in 2004, FDA concluded in its qualified health claim review that there is supportive, but not conclusive, research to suggest that  $n-3$  polyunsaturated fatty acids (EPA and DHA) reduce the risk of CHD (Ref. 59). Results of one clinical trial on the effects of EPA published since 2004 fail to demonstrate a significant reduction in the hazard ratio for the primary prevention of major coronary events (Ref. 60).

More recently, the 2010 DGAC concluded that moderate evidence shows that the consumption of two servings of seafood per week, which provides an average of 250 mg/d of long-chain  $n-3$  polyunsaturated fatty acids (i.e., EPA and DHA), is associated with reduced cardiac mortality from CHD or sudden deaths, both in persons with and without CVD (Ref. 30). The DGAC also concluded that the evidence for plant-derived  $n-3$  polyunsaturated fatty acids (i.e.,  $\alpha$ -linolenic acid) in reducing mortality among persons with existing CVD is limited (Ref. 30). Similarly, there is no conclusive evidence for an independent role of  $n-6$  polyunsaturated fatty acids in reducing blood cholesterol levels and, consequently, the risk of CHD. Evidence suggests that the benefit of  $n-6$  polyunsaturated fatty acids is observed only as a result of a reduction in saturated fatty acid intake (Refs. 6 and 59). The IOM noted that the evidence for a

role of EPA and DHA in CHD risk is growing (Ref. 49), but set AIs and AMDRs for  $\alpha$ -linolenic acid, not for EPA or DHA.

While a "healthy"  $\underline{n}$ -6: $\underline{n}$ -3 ratio may be important in human health, such a ratio has not been defined and much of the available evidence is based on studies conducted in animals, infants, and patients on total parenteral nutrition and much of the evidence in adults has come from observational studies (Ref. 49).

Because of the lack of well-established evidence for a role of  $\underline{n}$ -3 or  $\underline{n}$ -6 polyunsaturated fatty acids in chronic disease risk and the lack of a quantitative intake recommendation, and consistent with the factors discussed in section I.C., we tentatively conclude that the declarations of  $\underline{n}$ -3 and  $\underline{n}$ -6 polyunsaturated fatty acids are not necessary to assist consumers to maintain healthy dietary practices. Accordingly, we are not proposing to provide for the individual declaration of either  $\underline{n}$ -3 or  $\underline{n}$ -6 polyunsaturated fatty acids on the Nutrition Facts label. Similarly, because of the lack of well-established evidence for a role of EPA and DHA in chronic disease risk and the lack of a quantitative intake recommendation, consistent with the factors discussed in section I.C., we tentatively conclude that the declarations of EPA and DHA are not necessary to assist consumers to maintain healthy dietary practices. Accordingly, we are not proposing to provide for the mandatory or voluntary declaration of EPA or DHA on the Nutrition Facts label. We request comment about whether there is an appropriate alternative analysis to the application of the factors in section I.C. regarding the individual declaration of  $\underline{n}$ -3 or  $\underline{n}$ -6 polyunsaturated fatty acids, as well as EPA or DHA.

## 5. Monounsaturated Fat

a. Voluntary Declaration--FDA regulations currently permit, but do not require, the declaration of monounsaturated fat (defined as cis-monounsaturated fatty acids (e.g., oleic acid))

on the Nutrition Facts label (§ 101.9(c)(2)(iii)). To determine whether any changes are needed to the provision for voluntary declaration, we considered recommendations in current consensus reports as well as comments received in response to the 2007 ANPRM (Ref. 47), in which we requested comment on whether declaration of monounsaturated fat should remain voluntary or be made mandatory.

In 2002, the IOM noted that there was no known independent role of monounsaturated fatty acids in preventing chronic disease (Ref. 49). The lack of an independent effect of monounsaturated fatty acids on heart disease risk was also substantiated in a 2004 FDA review of a qualified health claim regarding monounsaturated fatty acids from olive oil and CHD (Ref. 61). Upon review of data related to this qualified health claim, we concluded that there was no evidence to indicate that monounsaturated fatty acids from olive oil, independent of saturated fatty acid displacement, lower serum total and LDL cholesterol levels. Most recently, the 2010 DGAC (Ref. 30) noted that there was strong evidence indicating that monounsaturated fatty acids are associated with improved blood lipids related to CVD when they replace saturated fatty acids. Consequently, the 2010 DGA recommends that most fats should be consumed as polyunsaturated and monounsaturated fatty acids (Ref. 6). Current dietary recommendations advise consumers to increase intakes of monounsaturated fatty acids to replace saturated fatty acids in their diets.

We acknowledge that monounsaturated fatty acids are not essential in the diet (Ref. 49). However, a lack of essentiality is not a basis for determining whether a nutrient should be required to be declared (see section I.C.). Indeed, nonessential nutrients trans fat, saturated fat, and cholesterol are required to be declared on the label because of their public health

significance. Scientific evidence points to the positive effects of increased monounsaturated fatty acid intake as a result of reduced intake of saturated fatty acids.

While a quantitative intake recommendation is not available from relevant U. S. consensus reports, there is well-established evidence to indicate that replacing saturated fatty acids with polyunsaturated and monounsaturated fatty acids reduces blood LDL cholesterol levels and, therefore, the risk of CVD, and that the prevalence of CVD is substantial in the United States (Ref. 30). We are not proposing any changes to the current requirement for mandatory declaration of saturated fat (see section II.B.2.). Because monounsaturated fat has public health significance when it replaces saturated fat, consistent with the factors we consider for voluntary declaration discussed in section I.C., we are proposing to continue to allow for voluntary declaration of monounsaturated fat, as provided in § 101.9(c)(2)(iii). We request comment about whether there is an appropriate alternative analysis to the application of the factors in section I.C. regarding the voluntary declaration of monounsaturated fat.

b. DRV--FDA regulations do not provide a DRV for monounsaturated fat. Current consensus reports do not provide specific quantitative intake recommendations for monounsaturated fatty acids. The IOM did not set a DRI for monounsaturated fatty acids because these fatty acids are not essential in the diet and have no known independent role in preventing chronic diseases (Ref. 49). Therefore, we tentatively conclude that there is no scientific basis on which we can rely to set a DRV for monounsaturated fat and, therefore, we are not proposing to set a DRV for monounsaturated fat.

### C. Cholesterol

#### 1. Mandatory Declaration

Section 403(q)(1)(D) of the FD&C Act requires the declaration of the amount of cholesterol on food labels, and cholesterol content must be declared on the Nutrition Facts label in accordance with § 101.9(c)(3). Current dietary recommendations continue to recognize the well-established relationship between consumption of cholesterol and its effect on blood cholesterol levels, which are a surrogate endpoint for CHD risk (Ref. 6). In addition, the 2010 DGA provided a quantitative intake recommendation for cholesterol (Ref. 6) (see discussion in this document). Furthermore, FDA authorized a health claim for dietary saturated fat and cholesterol and risk of CHD, for which we evaluated the scientific evidence on the association between dietary cholesterol and serum cholesterol levels (§ 101.75).

We are unaware of evidence that would support a change to the requirement for mandatory declaration of cholesterol on the Nutrition Facts label in § 101.9(c)(3) and, therefore, we are not proposing any changes to the current requirement for mandatory declaration.

## 2. DRV

FDA regulations provide a DRV for cholesterol of 300 mg (§ 101.9(c)(9)). The IOM Labeling Committee recommended, based on the IOM DRIs, that the DV for cholesterol (along with saturated fat and trans fat) should be set at a level that is as low as possible in keeping with an achievable health-promoting diet (Ref. 25 ). The IOM Labeling Committee suggested that FDA use food composition data, menu modeling, and data from dietary surveys to estimate minimum intakes that are consistent with nutritionally adequate and health-promoting diets for diverse populations (Ref. 25). Acknowledging these IOM recommendations, in the 2007 ANPRM, we asked for public comment on (1) whether the current DRV for cholesterol of 300 mg should be retained; and (2) whether food composition data, menu modeling, and data from dietary surveys should be used to establish a DRV for cholesterol that is as low as possible while

consuming a nutritionally adequate diet. We considered recommendations in current consensus reports as well as comments received (Ref. 47).

The 2010 DGA recommends consuming less than 300 mg/d of cholesterol to help maintain normal blood cholesterol levels and reducing intake to less than 200 mg/d for individuals at high risk of CVD (Ref. 6). The IOM also reported a relationship between increased cholesterol intake and increase in serum cholesterol, a surrogate endpoint for CHD risk (Ref. 62). The IOM macronutrient report recommended that cholesterol intakes should be as low as possible while consuming a nutritionally adequate diet, but did not set ULs for cholesterol (Ref. 62). Based on the reasons set forth previously, we disagree with the comments suggesting that a DRV of 300 mg is too low or that there is no strong association between cholesterol intake and CHD risk, or that current science justifies eliminating the percent DV declaration.

We do not agree with the IOM recommendation that food composition data, menu modeling, and data from dietary surveys offer a suitable approach for determining DRVs. Limitations inherent to menu modeling and food composition and dietary survey data sources are discussed in sections II.B.2.c. and II.B.3.c. We established the current DRV for cholesterol based on quantitative intake recommendations that considered specific effects on health outcomes (e.g., CHD) (58 FR 2206 at 2217). Use of menu modeling to determine a quantitative intake recommendation for cholesterol is inconsistent with this approach and may result in a reference intake level that is not based on scientific evidence related to actual public health outcomes.

Although the 2010 DGA recommends that cholesterol intake levels should be less than 200 mg/d for individuals at high risk of CVD, we consider the DGA recommendation of 300 mg/d for maintaining normal blood cholesterol levels as an appropriate basis for setting a DRV

because it represents the maximum intake level that covers the general U. S. population 4 years of age and older. Therefore, we are not proposing any changes to the DRV for cholesterol of 300 mg specified in § 101.9(c)(9).

#### D. Carbohydrate

In this section, we discuss our consideration of provisions related to definitions, declarations, DRVs, and analytical methods for total carbohydrate, total sugars, added sugars, dietary fiber, soluble and insoluble fiber, sugar alcohols, and other carbohydrates.

##### 1. Total Carbohydrate

a. Calculation of Total Carbohydrate--For the purposes of the Nutrition Facts label, total carbohydrate content is calculated by subtracting the sum of protein, total fat, moisture, and ash from the total weight of the food (§ 101.9(c)(6)). This calculation method is called "carbohydrate by difference" and is described in A.L. Merrill and B.K. Watt, "Energy Value of Foods-Basis and Derivation," in the USDA Handbook No. 74 (Ref. 63). Total carbohydrate includes starch, sugars, sugar alcohols, and dietary fiber.

On July 8, 2004, the National Starch and Chemical Company (National Starch) submitted a citizen petition requesting that dietary fiber content be excluded from the calculation of total carbohydrate that is declared on the Nutrition Facts label (Docket No. FDA-2004-P-0094) (<http://www.regulations.gov/#!docketDetail;D=FDA-2004-P-0094>). The petition noted that consumers wishing to reduce their intake of carbohydrate may also be inadvertently decreasing their consumption of high fiber foods, such as whole grains, because dietary fiber is included in the definition of "Total Carbohydrate." National Starch, therefore, requested an amendment to the second sentence in § 101.9(c)(6) to read as follows: "Total carbohydrate content shall be calculated by subtraction of the sum of the crude protein, total fat, moisture, ash, and dietary

fiber from the total weight of the food." The petition noted that excluding dietary fiber from the definition would be consistent with the way the IOM DRI report and Codex guidelines refer to carbohydrates and would be a more accurate representation of the amount of calories contributed by carbohydrates. To support this request, the petition presented study findings reported in the New York Times in 2004 and from research conducted on the internet. In addition, the petition discussed the use of the term "net carbs" in labeling and discussed inconsistencies in the way different manufacturers define the term "net carbs." According to the petition, some manufacturers define "net carbs" as the amount of total carbohydrate excluding the amount of dietary fiber and sugar alcohols while others exclude sugar alcohols and "other carbohydrates," as specified in § 101.9(c)(6)(iv), or sugar alcohols and "certain other carbohydrates." The petition suggested that the varied approaches to describing carbohydrates have led to consumer confusion.

In the 2007 ANPRM, we asked for comment on whether the approach for calculating total carbohydrate by difference should be retained and, if not, which specific components should be included or excluded from the calculation of total carbohydrate. In addition, acknowledging the 2005 DGA recommendation to consume fiber-rich foods, we asked for comment on whether separating dietary fiber from the amount of total carbohydrate would affect consumer understanding and use of the information, particularly with respect to fiber consumption. We received several comments (Ref. 47).

We reviewed scientific evidence and considered the petition's requests and comments received. As explained in this document, we decline to change to the current method for calculating total carbohydrate by difference.

Under FDA regulations, compliance with certain nutrition labeling requirements may be achieved by the use of an FDA-approved database (§ 101.9(g)(8)). Nutrient databases include carbohydrate values that are determined by difference. Changing the way carbohydrate is calculated would either necessitate an analogous change to the way carbohydrate is calculated in major nutrient databases, such as the USDA National Nutrient Database for Standard Reference, or would substantially decrease the usefulness of these databases in assisting manufacturers in making nutrient content declarations.

We also considered an alternative approach of calculating total carbohydrates by summing individual carbohydrate measurements rather than calculating by difference, as suggested by a comment. There is variability and error that are introduced with each analytical test that is performed (Ref. 64). When summing the values from the various tests, the amount of variability and error would multiply and such an approach is likely to result in greater variability and error. As discussed in the documentation for USDA's National Nutrient Database for Standard Reference, Release 23, when the analyses of starch, sugars, sugar alcohol, and dietary fiber are performed separately, the result reflects the analytical variability inherent to each of those measurement processes (Ref. 65). Thus, such an approach does not provide any distinct advantage over measuring carbohydrate by difference.

With respect to removal of dietary fiber from the calculation of total carbohydrate, we agree that the IOM provided separate DRIs for carbohydrate (i.e., starch and sugars) and dietary fiber. However, the IOM DRI Report does not provide recommendations for nutrition labeling. Furthermore, the report defines dietary fiber as "non-digestible carbohydrates and lignin that are intrinsic and intact in plants" (Ref. 66). Thus, the report acknowledges that dietary fibers, with the exception of lignin, are carbohydrates. As discussed in section II.D.5., the definition of

dietary fiber adopted by Codex in 2010 specifies that dietary fibers are carbohydrate polymers (Ref. 67). The Codex Guidelines on Nutrition Labeling, however, indicate that the nutrient declaration for carbohydrate should be "available carbohydrate," which is the amount of dietary carbohydrate, excluding dietary fiber (Ref. 67).

The petition states that the inclusion of dietary fibers in the calculation of total carbohydrate is not fully aligned with the Codex Guidelines on Nutrition Labeling. Our rationale for including dietary fiber in the calculation of total carbohydrate is based on what is considered to be a carbohydrate. To the extent the petition is requesting the removal of dietary fiber from the total carbohydrate calculation due to its physiological effects, we consider in greater detail in this document the classification and declaration of carbohydrates based on their chemical definition or their physiological effects. As discussed in greater detail in this document, we find that inclusion of dietary fiber in the determination of the label declaration of total carbohydrate is scientifically sound based on our chemical definition of total carbohydrate and the analytical methods used to determine carbohydrate content, as well as being consistent with the way subcategories of other macronutrients, such as fat, are listed on the Nutrition Facts label. Dietary fiber is a subset of carbohydrates. All dietary fibers, with the exception of lignin, are carbohydrate polymers. Although lignin is not a carbohydrate, it is tightly bound to other dietary fibers and cannot be easily isolated using AOAC or equivalent methods. It is, therefore, included in the calculation of total carbohydrate.

Further, dietary fiber is a mandatory separate listing on the Nutrition Facts label. Therefore, for consumers who wish to know the carbohydrate content of a food that excludes dietary fiber, this information can be deduced by subtracting the declared amount of dietary fiber from the declared amount of total carbohydrate on the Nutrition Facts label.

In addition, a calculation based on eliminating dietary fiber content from the declared value of total carbohydrate would necessitate calculating total carbohydrate by difference using the current method and then subtracting from that number the amount of dietary fiber obtained from separate analysis. This option presents a challenge with respect to the use of existing databases in the United States, which include dietary fiber in the calculation of total carbohydrate.

Moreover, the petition provided no references to (and we could not locate) the studies identified in the petition. We have no data or information at this time to indicate that removal of dietary fiber from the declaration of total carbohydrate would promote consumption of dietary fiber due to lower amounts of carbohydrate contents declared in nutrition labeling. Finally, to the extent that the petition seeks to define the term "net carbs," such a request is outside the scope of this rulemaking. In this proposed rule, we are considering whether to propose a change in how "total carbohydrate" is calculated. Therefore, to the extent the petitioner is requesting to remove "dietary fiber" from the total carbohydrate calculation to prevent consumer confusion from the term "net carb," we decline to change the calculation of total carbohydrate by difference on that basis. We consider the calculation and declaration of "net carbs" and the total carbohydrate calculation and declaration on the label as separate and distinct. The declaration of total carbohydrate is required under section 403(q)(1)(D) of the FD&C Act.

For these reasons, we decline to change the method for calculating total carbohydrate by difference and, therefore, we are not proposing any changes to the method for calculating total carbohydrate by difference specified in § 101.9(c)(6).

b. Classification of Carbohydrates Based on a Chemical Definition or Physiological Effect--In the 2007 ANPRM, we asked for comment on whether carbohydrates should be

classified and declared in nutrition labeling based on their chemical definition (current method) or on their physiological effect (e.g., attenuation of blood sugar or laxation if dietary fiber were to be included in the total carbohydrate declaration), and whether additional types of carbohydrates (e.g., starch) should be listed separately on the Nutrition Facts label. We received several comments (Ref. 47) in response to these questions.

We considered this issue in light of the comments received. We agree with the comments that stated that classification of carbohydrates based on validated analytical techniques, which isolate and measure the individual carbohydrates based on their chemical structure rather than based on their physiological effects, is necessary for determining the accuracy of values declared on the label. Carbohydrates include starch, sugars, sugar alcohols, and dietary fibers. Different types of carbohydrates have different physiological effects. The effects of some carbohydrates are not fully understood and are the subject of debate in the scientific community. Within the different types of carbohydrate (i.e., starch, sugars, sugar alcohols, and dietary fibers), too, specific carbohydrates may have different physiological effects (e.g., different types of dietary fibers) making it difficult to apply a definition that is based on physiological effects across a category of carbohydrates. Furthermore, analytical methods for measuring different types of carbohydrates are based on chemical structure rather than physiological effect. Given the various components of total carbohydrate and different types of physiological effects of each, we disagree that a definition based on "physiological effects" would be a better approach than a chemical definition for total carbohydrate declaration. The use of a chemical definition is also consistent with the classification and declaration of fat on the Nutrition Facts label. Different types of fats identified in nutrition labeling are not classified based on their physiological effect but rather on their chemical definition.

Therefore, we are not proposing to use physiological effects of carbohydrates as a basis for classifying or declaring total carbohydrate. Accordingly, we are not proposing to change our provisions for the classification or declaration of carbohydrates specified in § 101.9(c)(6).

c. Separate Declaration of Additional Individual Types of Carbohydrates--In the 2007 ANPRM, we asked whether additional types of carbohydrates (e.g., starch) should be listed separately on the Nutrition Facts label. We considered comments received (Ref. 47), which, taken together, did not support declaration of additional types of carbohydrates. Some comments stated that such additional information could distract consumers from information that is important, such as dietary fiber. A few comments that supported the declaration of starch provided no evidence to support their assertions regarding the benefit of this declaration for diabetics. Moreover, there is no strong scientific evidence for us to consider related to the role of starch in human health. Therefore, we are not proposing to require the separate declaration of additional types of individual carbohydrates such as starch on the Nutrition Facts label.

d. Mandatory Declaration--Section 403(q)(1)(D) of the FD&C Act requires the declaration of total carbohydrate. Correspondingly, regulations require the declaration of the amount of total carbohydrate on the Nutrition Facts label (§ 101.9(c)(6)). Carbohydrates are an essential part of the diet because they provide energy to the cells in the body, especially the brain, which is dependent on carbohydrate for proper functioning (Ref. 68). We have no basis on which to reconsider the requirement for mandatory declaration of the amount of total carbohydrate on the Nutrition Facts label and comments in response to the 2007 ANPRM also supported this mandatory declaration. We tentatively conclude that the declaration of carbohydrates on the Nutrition Facts label continues to be necessary to assist consumers in maintaining healthy dietary practices. Therefore, we are not proposing any changes to the

current requirement for mandatory declaration of total carbohydrate, as specified in § 101.9(c)(6).

e. DRV--The DRV for total carbohydrate is 300 g (§ 101.9(c)(9)). The IOM established an AMDR for carbohydrate intake of 45 to 65 percent of energy for adults and an EAR of 100 g/d for adults and children (Ref. 69). In the IOM report, "carbohydrate" only included starch and sugars, not sugar alcohols or dietary fiber. The IOM also set the RDA for "carbohydrate" (i.e., starch and sugars) at 130 g/d for adults and children based on the average minimum amount of glucose utilized by the brain in adults, which was extrapolated to children ages 1 through 18 years. Subsequently, the IOM Labeling Committee recommended that, as in the case of protein and total fat, the AMDRs should be the basis for DVs for total carbohydrate (Ref. 25). Considering that AMDRs vary with age, the IOM Labeling Committee recommended a population-weighted midpoint of the AMDR. Under this approach, using a population-weighted mid-point of the AMDR for adults and children, i.e., 45 to 65 percent, the DV for total carbohydrate would amount to 55 percent or, based on a 2,000 calorie reference calorie intake, 275 g of carbohydrate.

However, as we noted in the 2007 ANPRM, the IOM's AMDR, EAR, and RDA values for carbohydrate do not include sugar alcohols or dietary fiber. In contrast, our calculation of total carbohydrates for the purposes of nutrition labeling accounts for all types of carbohydrates, including sugar alcohols and dietary fiber. Therefore, applying the IOM Labeling Committee's approach, in which a DV is derived from the AMDR, would result in a reference value based on recommendations specifically for sugars and starches, whereas the absolute gram amount of carbohydrates declared on the label includes all carbohydrates. Consequently, if the midpoint of the AMDR range is used as the basis for the DRV, there would be a discrepancy in what

carbohydrates are encompassed in the information provided on the label for the absolute gram amount versus the percent DV. We did not ask any questions about the DRV for total carbohydrate in the 2007 ANPRM nor did we receive any comments on this issue. Consistent with calculating total carbohydrate "by difference" (discussed previously), we are proposing no changes to the approach to calculate the percent DV for carbohydrate "by difference" as well. In addition, we are not proposing to change the DRVs for fat or protein (see sections II.B. and II.E.), which are used to derive the DRV for total carbohydrate. Therefore, we are not proposing any changes to the DRV for total carbohydrate of 300 g/d. We note that the RDA for carbohydrate for men and women 19 years of age and older is 130 g/d. Therefore, the DRV should not be viewed as an intake requirement, but as a reference amount.

f. Calculation of Calories From Carbohydrate--FDA regulations require that the calories from total carbohydrate be calculated by using the general factor of 4 calories/g of carbohydrate less the amount of insoluble dietary fiber (§ 101.9(c)(1)(i)(C)). We are proposing a new definition of dietary fiber (see section II.D.5.a.i.) that only allows for the declaration of dietary fibers that we have determined to have a physiological effect that is beneficial to human health, as "dietary fiber" on the Nutrition Facts label. Therefore, the new definition of dietary fiber would exclude both soluble and insoluble non-digestible carbohydrates that do not meet the proposed definition. For the purposes of calculating calories from carbohydrate, all soluble and insoluble non-digestible carbohydrates should be excluded from the calculation, not just those known to meet the definition of dietary fiber. To ensure that all soluble and insoluble non-digestible carbohydrates are excluded from the calculation of calories from carbohydrate, we are proposing to amend § 101.9(c)(1)(i)(C) to require that calories from carbohydrate be calculated using a general factor of 4 calories/g of total carbohydrate less the amount of non-digestible

carbohydrates. As discussed in section II.D.5.b.v., a value of 2 calories/g of soluble non-digestible carbohydrates is then added to the calculation.

## 2. Sugars

a. Definition--Sugars are defined in § 101.9(c)(6)(ii) as a statement of the number of g of sugars in a serving. They are the sum of all free mono and disaccharides (e.g., glucose, fructose, lactose, and sucrose). We received a citizen petition on the term "sugars" and, as explained in this document, we are not proposing any changes to the term or its definition for the purpose of nutrition labeling.

b. Mandatory Declaration--Section 403(q)(1)(D) of the FD&C Act requires the declaration of sugars. FDA regulations require the declaration of sugars on the Nutrition Facts label (§ 101.9(c)(6)(ii)).

The Sugar Association submitted a citizen petition on August 16, 2005 (Docket No. FDA-2005-P-0373) requesting among other things that we eliminate "sugars" as a mandatory nutrient that is declared on the Nutrition Facts label or, alternatively, rename "sugars" as "sugars/syrup" and require the mandatory declaration of polyol and artificial sweeteners on the Nutrition Facts label, as well as the mandatory labeling of each specific polyol and artificial sweetener ingredient and its amount on the food label (<http://www.regulations.gov/#!docketDetail;D=FDA-2005-P-0373>). The petition asserted that consumers understand "sugars" to mean sucrose. The petition stated that an increasing number of manufacturers are using artificially produced (alternative) sweeteners, such as high fructose corn syrup, instead of sucrose products such as table sugar. The petition also asserted that, under current regulations, information on sugar content is presented in a manner that is misleading to consumers because it does not reflect the caloric content of artificially produced sweeteners and

does not identify the specific sweeteners used in food products. The petition also expressed concern about the potential caloric and health effects of alternative sweeteners and asserted that the current labeling of sugar and lack of labeling for artificially produced sweeteners on the Nutrition Facts label did not provide consumers with relevant information about alternative sweeteners. However, the petitioner did not include any data to specifically support these assertions and concerns.

In the 2007 ANPRM, we requested comment on whether "sugars" should continue to be included on the Nutrition Facts label. We received several comments which were in favor of continuing to require mandatory labeling of sugars on the Nutrition Facts label (Ref. 47).

We considered the petition and comments received in light of scientific evidence. There is strong and consistent evidence based on valid endpoints that consumption of sugars is associated with an increased risk of dental caries (Refs. 6 and 68). We authorized a health claim for dietary non-cariogenic carbohydrate sweeteners and dental caries (§ 101.80). The IOM macronutrient report noted that dental caries is a condition of public health concern that is associated with consumption of sugars (Ref. 68). Therefore, we tentatively conclude that the declaration of sugars continues to be necessary to assist consumers in maintaining healthy dietary practices, and we are not proposing to change the current requirement for mandatory declaration of sugars.

Moreover, we decline the petition's request to rename "sugars" as "sugars/syrups" on the Nutrition Facts label. The petition requested that we rename the "sugars" category to prevent consumers from being misled with regard to the ingredients that are permitted to be considered sugars under the current regulation (monosaccharides plus disaccharides such as high fructose corn syrup). The petition, however, did not provide data or information to support the assertion

that consumers are misled by the term "sugars" on products containing sweeteners that are a combination of mono and disaccharides, as defined in § 101.9(c)(6)(ii). We are considering using the term "total sugars" in lieu of "sugars" on the Nutrition Facts label if "added sugars" declaration is finalized, as proposed. FDA plans to conduct consumer testing of the terms "total sugars" and "sugars" on the Nutrition Facts label (FR 2013–12824) to determine if use of the term "total sugars" aids consumers in understanding that added sugars are part of the total amount of sugars in product.

We also decline the petition's request to require manufacturers to declare the specific type of artificial sweetener used on the Nutrition Facts label so that consumers can be made aware of the degree of substitution, when artificial sweeteners are substituted for sugars, and the overall level of the artificial sweeteners in the food. Under FDA regulations, artificial sweeteners that are added to a food are required to be declared in the ingredient statement of the label. The petition did not provide any justification that additional information about artificial sweeteners in nutrition labeling is warranted and we have no data to suggest that a declaration of artificial sweeteners is necessary to assist consumers in maintaining healthy dietary practices.

Therefore, we are not proposing any change to the current requirement for mandatory declaration of sugars on the Nutrition Facts label, as specified in § 101.9(c)(6)(ii). We are also not proposing to rename the "sugars" category as "sugars/syrups" or require the mandatory declaration of specific sugar alcohols or other artificial sweeteners.

c. DRV--FDA regulations do not specify a DRV for sugars. Current consensus reports have not set dietary reference values based on which we could derive an appropriate DRV for total sugars. While the IOM found an association between sugar consumption and risk of dental caries, due to the various factors that contribute to dental caries, IOM could not determine an

intake level of sugars that is associated with increased risk of dental caries and, therefore, did not have sufficient evidence to set a UL for sugars (Ref. 68). We did not ask any questions related to the DRV for sugars in the 2007 ANPRM nor did we receive any comments recommending the establishment of a DRV for total sugars. For these reasons, we are not proposing to establish a DRV for total sugars.

### 3. Added Sugars

a. Declaration--FDA regulations neither define the term "added sugars" nor require or permit its declaration on the Nutrition Facts label. We are reconsidering the declaration of added sugars taking into account new data and information, including U. S. consensus reports and recommendations related to the consumption of added sugars, a citizen petition submitted by the CSPI, and public comments. For the purposes of the discussion in this document, added sugars refer to sugars and syrups that are added to foods during processing or preparation (Ref. 6).

i. Consensus Reports. The IOM DRI Report on Macronutrients stated that "although added sugars are not chemically different from naturally occurring sugars, many foods and beverages that are major sources of added sugars have lower micronutrient densities compared to foods and beverages that are major sources of naturally occurring sugars" (Ref. 68). Although an upper level was not set for total or added sugars, a maximal intake level of 25 percent or less of energy from added sugars was suggested based on data that demonstrated decreased intakes of some micronutrients among American subpopulations whose intake of added sugars exceeded this level.

In addition, the 2010 DGA (Ref. 6) noted that the primary prevention of obesity, especially in childhood, is an important strategy for combating and reversing the obesity epidemic. Over the last few decades, the prevalence of overweight and obese individuals in the

United States dramatically increased among children, adolescents and adults. Many factors contribute to weight gain and obesity but maintaining an appropriate calorie balance and increasing physical activity and reducing sedentary behaviors are key recommendations to help combat the problem. The 2010 Dietary Guidelines Advisory Committee (DGAC) concluded that strong evidence shows that children who consume more sugar-sweetened beverages have greater adiposity (body fat) compared to those with a lower intake. The sole source of calories in many sugar-sweetened beverages (e.g., soda) is added sugars. The 2010 DGA specifically suggest that reducing the intake of sugar-sweetened beverages may help individuals control their total calorie intake and manage their body weight. The report stated that Americans consume too many calories from solid fats (fats containing a high percentage of saturated and trans fatty acids and are solid at room temperature) and added sugars and these foods replace nutrient-dense foods and beverages and make it difficult for people to achieve the recommended nutrient intake while controlling their calorie intake. Together, solid fats and added sugars contribute a substantial portion of Americans' calories, 35 percent on average (16 percent total on average from added sugar) without contributing to the overall nutrient adequacy of the diet and thus have implications for weight management. Thus, to meet nutrient needs within an individual's calorie limits, a key recommendation of the 2010 DGA is to reduce the intake of calories from solid fats and added sugars.

The report recognized that foods containing solid fats and added sugars are no more likely to contribute to weight gain than any other source of calories in an eating pattern that is within calorie limits. However, reducing the consumption of calories from solid fats and added sugars allows for increased intake of nutrient-dense foods without exceeding overall calorie needs. The report recommended several ways to reduce the consumption of solid fats and added

sugars including eating the most nutrient-dense forms of foods from all food groups, limiting the amount of solid fats and added sugars when cooking or eating, and consuming fewer and smaller portions of foods and beverages that contain solid fats and added sugars. Specifically, the 2010 DGA noted that, for most people, no more than about 5 to 15 percent of calories from solid fats and added sugars can be reasonably accommodated in the USDA Food Patterns, which are designed to meet nutrient needs within calorie limits. The 2010 DGA also outlined common elements of healthy eating patterns and stated that reducing the intake of added sugars is one component.

Although the subject of front-of-package labeling (FOP) is outside the scope of this proposed rule, we reviewed the IOM Front-of-package Nutrition Rating Systems and Symbols Committee's final report for their conclusions on scientific evidence related to the effect of added sugars on human health. This Committee cited the 2010 DGA recommendations related to added sugars and noted that while there is a lack of scientific agreement on the effects of added sugars on health outcomes independent of the effects of total sugar, there is adequate evidence that added sugars (whether a solid or liquid) contribute extra calories to a diet, which could in turn lead to weight gain and obesity (Ref. 28).

ii. CSPI Petitions. We received a petition from CSPI on August 3, 1999 (hereafter referred to as "the 1999 CSPI petition") requesting that we require the Nutrition Facts label to disclose the quantity of added sugars present in packaged foods and to set a DRV for refined sugars added to foods (Docket No. FDA-1999-P-0158) (<http://www.regulations.gov/#!docketDetail;D=FDA-1999-P-0158>). The petition stated that the DRV for added sugars should be 40 g based on USDA's "Food Guide Pyramid" recommendations that Americans should limit their daily intake of added sugars to about ten

teaspoons (40 g) for a 2,000 calorie healthful diet. The petition cited USDA Economic Research Service's data that show that the per capita consumption of added sugars rose by 28 percent from 1983 to 1999 (Ref. 70). The petition also referred to evidence that added sugars may contribute to obesity and heart disease, and argued that it is impossible for consumers to determine how much sugar has been added to foods or how much added sugars are reasonable to consume because the Nutrition Facts label does not currently provide this information. Although the petition also requested that we amend our regulations to prescribe nutrient content claims and health claims related to "added sugars," those requests are not considered within the scope of this proposed rule. We received another petition from CSPI on February 13, 2013 (hereafter referred to as "the 2013 CSPI petition"), requesting that we revise the "sugars" line of the Nutrition Facts label to address "added sugars." (Docket No. FDA-2013-P-0217) (<http://www.regulations.gov/#!docketDetail;D=FDA-2013-P-0217>). CSPI described "added sugars" as "various caloric sweeteners," including sucrose, high-fructose corn syrup, corn sugar, invert sugar, corn syrup "and others." We address CSPI's request for an "added sugar" declaration in this proposed rulemaking. The data and information provided by the 2013 CSPI petition in regards to added sugar declaration does not change our current considerations or rationale for mandating added sugars on the label that are addressed in this document. Although CSPI included other requests in its petition, which generally relate to lowering levels of added sugars in foods, we do not address those requests in the context of this proposed rule because they are outside the scope of this proposed rule.

iii. Public Comments. On June 26, 2000, we published a notice of availability of the 1999 CSPI petition in the Federal Register and requested comment (65 FR 39414). We received more than 2,700 comments from individuals, industry, academic institutions, advocacy groups,

and health care groups. Several comments stated that added sugar declaration should be voluntary and not mandatory (Ref. 47). We did not ask any questions on added sugars in the 2007 ANPRM. However, we received comments that supported and others that opposed the declaration of added sugars on the Nutrition Facts label (Ref. 47).

iv. FDA's Considerations and Proposal. A key recommendation of the 2010 DGA is to reduce the intake of calories from solid fats and added sugars. A high intake of calories from excess solid fat and added sugars can decrease the intake of nutrient-rich foods in the diet and can increase the overall caloric intake which could lead to weight management issues. As such, this key recommendation feeds into two overarching concepts of the intent of the Dietary Guidelines of maintaining calorie balance over time to achieve and sustain a healthy weight as well as supporting consumption of nutrient-dense foods (Ref. 6). As discussed in this document, a declaration of added sugars on the Nutrition Facts label would assist consumers in maintaining healthy dietary practices by providing them with information necessary to meet the key recommendations to construct diets containing nutrient-dense foods and reduce calorie intake from added sugars by reducing consumption of added sugars.

The Nutrition Facts label includes the mandatory declaration of the fatty acids that are contained in solid fats from the DGA recommendation, in that saturated fatty acids and trans fatty acids are required to be declared on the Nutrition Facts label. Solid fats are solid at room temperature and contain a mixture of saturated and unsaturated fatty acids but tend to contain a high percentage of saturated or trans fatty acids. The disclosure of saturated fat and trans fat on the label not only provides information to consumers for managing their effects on CVD (see sections II.B. and II.C.) but also could provide a marker for foods that contain solid fats that are abundant in the diets of Americans and contribute significantly to excess calorie intake (Ref. 6).

However, similar information about added sugars is not currently available on the Nutrition Facts label. Thus, we are proposing to require the declaration of added sugars on the Nutrition Facts label to provide consumers with information that is necessary to meet the dietary recommendation to reduce caloric intake from solid fats and added sugars.

Added sugars contribute an average of 16 percent of the total calories in American diets (Ref. 6). According to NHANES, the major sources of added sugars in the diet in descending order are soda, energy and sports drinks, grain based desserts, sugar-sweetened fruit drinks, dairy-based desserts and candy. Most of these foods are not nutrient-dense and may add calories to the diet without providing dietary fiber or essential vitamins and minerals (Ref. 6). The consumption levels of added sugars alone exceed the discretionary calorie recommendations of 5 to 15 percent of calories from both solid fats and added sugars discussed in the 2010 DGA. Although foods containing solid fats and added sugars do not contribute to weight gain any more than another calorie source, they make up a significant percentage of the American diet and are a source of excess calories. The 2010 DGAC concluded that strong evidence shows that children who consume sugar-sweetened beverages have increased adiposity (increased body fat). The 2010 DGAC also concluded that there is a moderate body of evidence suggesting that greater consumption of sugar-sweetened beverages is associated with increased body weight in adults and that under isocaloric controlled conditions, added sugars, including sugar-sweetened beverages, are no more likely to cause weight gain in adults than any other source of energy. While the IOM FOP report did not review scientific data on added sugars, based on the 2010 DGA recommendation to reduce intake of calories from added sugars, it concluded that added sugars should be included in an FOP labeling system. In addition the IOM FOP committee recommended that the FOP symbol system should be integrated with the Nutrition Facts label so

that the two are mutually reinforcing. The IOM DRI Macronutrient Report noted the difficulty, among some populations, of consuming adequate amounts of certain micronutrients when excessive amounts of added sugars are consumed.

As the CSPI petition pointed out, other groups such as the American Heart Association (AHA), American Academy of Pediatrics, and World Health Organization (WHO) have recommended limiting added sugars consumption. None of these recommendations was based on an increased risk of obesity or heart disease. Both the AHA and American Academy of Pediatrics recommendations point out that added sugars intake is associated with a greater intake of calories and a lower intake of essential nutrients, whereas the 1990 WHO recommendation for decreasing added sugars is based on dental caries and that excessive consumption of these sugars can displace nutrient-containing foods in the diet (Refs. 71 to 73). While these groups are not recognized as U. S. consensus groups by FDA, these recommendations support our proposal to require the mandatory declaration of added sugars so that consumers can achieve a dietary pattern that is nutrient-dense and that does not exceed caloric needs from added sugars, consistent with the 2010 DGA recommendations.

Further, we consider it necessary to require a declaration of added sugars for all foods for which a Nutrition Facts label is required. Using the current label, consumers cannot identify or compare the amounts of added sugars to enable them to follow the recommendation of the 2010 DGA. We are proposing mandatory declaration of added sugars on all foods because of (1) the variability in ingredients used, (2) the need for consumers to have a consistent basis on which to compare products, (3) the need for consumers to identify the presence or absence of added sugars, and (4) when added sugars are present, the need for consumers to identify the amount of added sugars added to the food. The mandatory declaration of added sugars may also prompt

product reformulation of foods high in added sugars like what was seen when trans fat labeling was mandated (Ref. 58).

We understand that our rationale to support an added sugars mandatory declaration in labeling is different from our rationale to support other mandatory nutrients to date which, consistent with the factors we describe in section I.C., generally relate to the intake of a nutrient and risk of chronic disease, a health-related condition, or a physiological endpoint. U. S. consensus reports have determined that inadequate evidence exists to support the direct contribution of added sugars to obesity or heart disease. Specifically, although it is recognized that sugar-sweetened beverages increase adiposity (body fat) in children (Ref. 30), neither the 2010 DGA nor the IOM macronutrient report concluded that added sugars consumption from all dietary sources, in itself, increases obesity. In fact, the 2010 DGA states that added sugars do not contribute to weight gain more than any other source of calories. The evidence submitted by CSPI supporting the contribution of added sugars to heart disease failed to show a direct association between added sugars consumption and heart disease risk. Rather, the evidence shows that the consumption of total carbohydrates (not added sugars, per se) is associated with an increase in serum triglyceride levels. Moreover, serum triglyceride level is not an endpoint that we recognize as a validated surrogate marker for CHD risk in our evidence-based review system for health claims (Ref. 74). Nevertheless, for the reasons explained previously that include providing consumers with the information necessary to follow the 2010 DGA recommendations to reduce the intake of calories from added sugars, we tentatively conclude that the declaration of added sugars is required to assist consumers in maintaining healthy dietary practices.

Additionally, in the absence of uniform added sugars declaration on the Nutrition Facts label, consumers would not be able to compare the added sugars content of foods, particularly those that contain both naturally occurring sugars and added sugars (e.g., yogurt and dairy-based desserts). Contrary to what one comment stated, the added sugars declaration in the ingredient statement of a food label may not provide sufficient or quantitative information for consumers to be able to formulate diets consistent with the dietary recommendations. Sugars may be added to foods in the form of various ingredients, such as fruit juice concentrates, fructose, maltose, sucrose, and honey, and consumers may not realize that these ingredients are, in fact, forms of added sugars and would not be able to determine the quantities added. Thus, as pointed out in some comments, calorie declaration and ingredient listing do not provide enough information for consumers to determine the amount of calories derived from added sugars in the food. We acknowledge that some products may contain only added sugars and no naturally occurring sugars (e.g., soda) and that the amount shown in the total "sugars" declaration on the Nutrition Facts label for such products would be the amount of added sugars. In this case, however, some consumers may still not be able to determine the amount of added sugars because the term would not appear on the label at all. At this point in time, we cannot be certain that most consumers would understand that, in the absence of added sugars declaration, all sugars in these products are added sugars. Therefore, without the added sugars declaration, some consumers may perceive the amount of added sugars in the product differently and some perceived amounts may differ from the actual amount in the product. Food formulations may vary and consistency in the mandatory declaration of added sugars is important so that consumers are not confused.

We recognize that small amounts of added sugars can increase the palatability of nutrient-dense foods, as suggested by a comment. The disclosure of added sugars on the label

may allow consumers to plan and construct their diets to include small amounts of added sugars and still consume adequate amounts of necessary nutrients. Consumers may select from a variety of such nutrient-dense foods as part of their overall dietary pattern in a way to reduce or minimize the caloric contribution of added sugars from such sources. The IOM FOP report noted that small amounts of added sugars would be appropriate for foods to earn FOP points in their recommended labeling scheme, which suggests that small amounts would be appropriate in a balanced diet (Ref. 29).

We acknowledge that, if finalized, a requirement for declaration of added sugars on the Nutrition Facts label will need to be accompanied by consumer education on the role of added sugars, along with solid fats, and the use of the new information on the label in overall dietary planning. We will be conducting consumer studies that include questions regarding including added sugars on the Nutrition Facts label. We plan to use the results of these studies to help inform our future actions on this issue.

We understand that there are currently no analytical methods that are able to distinguish between naturally occurring sugars and those sugars added to a food. However, we do not agree with comments that analytical limitations should preclude mandatory declaration of added sugars because there is an alternative method to assess compliance. The amount of added sugars declared on the label could be verified through means other than chemical analysis, such as through maintenance and review of records. The reliance on records for compliance purposes is not unique to added sugars as we have previously required that manufacturers provide records under certain circumstances to support statements made on food labels (for example, with respect to aeration to reduce fat and caloric content of foods (58 FR 2229 at 2271) and caloric content of new products with reduced digestibility (58 FR 2079 at 2111)). In addition, in sections II.D.5.,

II.J.2., and II.J.3., we are proposing to use records to determine compliance with declared values of dietary fiber, folate, and vitamin E, under certain specified circumstances.

We continue to recognize the lack of a physiological distinction between added and naturally occurring sugars. While comments expressed concerns that declaration of added sugars could significantly under-represent the sugars content of many foods with a large quantity of naturally occurring sugars, we are not proposing to remove the total sugars declaration (see section II.D.2.) because there continues to be strong scientific evidence linking total sugars intake with dental caries. Therefore, the sugar content of foods with naturally occurring sugars would not be under-reported.

We also considered the appropriateness of voluntary declaration of added sugars, an approach supported by several comments. However, we are concerned that voluntary declaration of added sugars may not ensure that consumers have the information that will allow them to follow the current dietary recommendations. Added sugars declared voluntarily by manufacturers on some products, but not on others, either within a given product category or across different product categories, could be confusing to consumers, and would not provide consumers with the information they need to plan their dietary pattern to reduce consumption of calories from added sugars.

In light of current dietary recommendations that advise Americans to reduce their intake of calories from added sugars, we consider that an added sugars declaration will help individuals identify foods that are nutrient-dense within calorie limits and aid in reducing excess discretionary calorie intake from added sugars. We tentatively conclude that the declaration of added sugars on the Nutrition Facts label is necessary to assist consumers to formulate diets consistent with current dietary recommendations and, thus, maintain healthy dietary practices.

Therefore, proposed § 101.9(c)(6)(iii) would require the mandatory declaration of added sugars as an indented line item underneath the declaration of total sugars on the Nutrition Facts label.

We invite comment on this issue. We also invite comment, including the submission of research on whether calories from added sugars should be declared on the Nutrition Facts label in lieu of a gram declaration of added sugars to aid consumers in maintaining healthy dietary practices.

FDA regulations require that the statement "Not a significant source of \_\_\_\_" for calories from fat, saturated fat, trans fat, cholesterol, dietary fiber, sugars, and protein must be placed at the bottom of the table of nutrient values in the same type size, under the specific circumstances described for each nutrient in § 101.9(c). For sugars, the phrase "Not a significant source of sugars" must be placed at the bottom of the table of nutrient values if a statement of the sugars content is not required and, as a result, not declared. A statement of sugars content is not required for products that contain less than 1 gram of sugars in a serving if no claims are made about sweeteners, sugars, or sugar alcohol content (§ 101.9(c)(6)(ii)). Similar information on added sugars could also be useful to consumers who are trying to limit their intake of added sugars. Therefore, proposed § 101.9(c)(6)(iii) would require that the phrase "Not a significant source of added sugars" be placed at the bottom of the table of nutrient values if a statement of the added sugars content is not required and, as a result, is not declared. We are also proposing that a statement of added sugars content would not be required for products that contain less than 1 gram of added sugars in a serving if no claims are made about sweeteners, sugars, or sugar alcohol content (proposed § 101.9(c)(6)(iii)).

In addition, for total carbohydrate, dietary fiber, soluble fiber, insoluble fiber, sugars, and sugar alcohol, when a serving of the food contains less than 1 gram of the nutrient, FDA regulations in § 101.9 permit the use the alternative statements "Contains less than 1 gram" or

"less than 1 gram," and if a serving of the food contains less than 0.5 grams of the nutrient, the content may be expressed as zero. Proposed § 101.9(c)(6)(iii) would provide for similar use of alternative statements, "Contains less than 1 gram" and "less than 1 gram" for added sugars. In addition, if the serving contains less than 0.5 g of added sugars, we are proposing to permit the content to be expressed as zero (proposed § 101.9(c)(6)(iii)).

b. Proposed Definition--The term "added sugars" is not defined in FDA regulations. Given our tentative conclusion to require mandatory declaration of "added sugars" on the Nutrition Facts label, we are proposing to define added sugars. In proposed § 101.9(c)(6)(iii), we are proposing to define "added sugars" as sugars that are either added during the processing of foods, or are packaged as such, and include sugars (free, mono- and disaccharides), syrups, naturally occurring sugars that are isolated from a whole food and concentrated so that sugar is the primary component (e.g., fruit juice concentrates), and other caloric sweeteners. This would include single ingredient foods such as individually packaged table sugar. Sugar alcohols are not considered to be added sugars. Names for added sugars include: Brown sugar, corn sweetener, corn syrup, dextrose, fructose, fruit juice concentrates, glucose, high-fructose corn syrup, honey, invert sugar, lactose, maltose, malt sugar, molasses, raw sugar, turbinado, sugar, trehalose, and sucrose. This proposed definition of added sugars includes what CSPI described as "added sugars" in the 2013 CSPI petition.

c. Daily Value--Given our proposal to require the declaration of added sugars, we also considered establishing a DRV for added sugars. In its 1999 petition as well as in a published report (Ref. 75), CSPI recommended that FDA base a DV for "added sugars" on suggested limits of added sugars published in the 1992 USDA's Food Guide Pyramid (Ref. 76). CSPI determined that a DRV for added sugars based on a 2,000 calorie diet would be 10 teaspoons or 40 g of

added sugars. Overall, comments submitted in response to CSPI's 1999 petition were in favor of this approach to setting a DRV for added sugars. Comments in response to the 2007 ANPRM also recommended establishing a DV for added sugars (Ref. 47).

We reviewed scientific evidence and recommendations of consensus reports, and disagree with the petitioner and comments that there is currently a sound scientific basis for the establishment of a quantitative intake recommendation upon which a DRV could be derived. The IOM did not set a DRI, such as a UL, for added sugars (Ref. 68). The IOM suggested that no more than 25 percent of energy should be consumed from added sugars, but noted that a defined intake level at which inadequate micronutrient intakes occur could not be identified. The 2010 DGA did not provide a quantitative intake recommendation for added sugars intake but did provide a maximum intake level for solid fats and added sugars at 13 percent of calories for a 2,000 calorie diet based on food pattern modeling of the USDA Food Patterns and also described the "DASH" (Dietary Approaches to Stop Hypertension) eating plan which recommends 5 servings or less per week of sweets and added sugars for a 2,000 calorie diet (Ref. 6). The USDA Food Patterns, which provide recommended amounts of foods from each food group that individuals should consume in order to meet their nutrient needs within a specific calorie level, specify that the maximum amount of calories from solid fats and added sugars that can be consumed at the 2,000 calorie level while staying within calorie limits is 258 calories (Ref. 6). The solid fats and added sugars limit at each calorie level in the USDA Food Patterns is determined by calculation through food pattern modeling rather than on any biomarker of risk of disease or other public health endpoint. However, an exact amount of calories for added sugars is not detailed in either the USDA Food Patterns or "DASH" eating plans, as they represent templates that translate and integrate dietary recommendations, rather than specific quantitative

intake recommendations (Ref. 6). Thus, we have no scientifically supported quantitative intake recommendation for added sugars on which a DRV for added sugars can be derived. Therefore, we are not proposing a DRV for added sugars. Accordingly, the proposed rule, if finalized, would declare added sugars on the Nutrition Facts label only in absolute amounts (in g), similar to the declaration of total sugars.

d. Compliance--As expressed in the preamble to the 1993 RDI/DRV final rule, we are not aware of an analytical method that is capable of distinguishing between added and intrinsically occurring sugars in a food product (58 FR 2206 at 2222). Thus, it is not technologically feasible for us to rely on an analytical method to determine compliance with the declaration of added sugars in foods that contain both added sugars and naturally occurring sugars. We recognize that enforcement of the mandatory declaration of added sugars content will require an alternative means of verifying compliance and are proposing in § 101.9(g)(10) to include records requirements related to the added sugars declaration in food. Similarly, in the other cases where there are not reliable and appropriate analytical methods that will allow us to verify the amount of a given nutrient in a food (dietary fiber, vitamin E (tocopherol), and folate), we are also proposing to require manufacturers make and keep certain records necessary to verify the amount of these nutrients present in a food (see proposed § 101.9(g)(10)). In the case of added sugars that are not subject to fermentation, when a mixture of naturally occurring and added sugars is present in the food, we are proposing that a manufacturer must make and keep written records of the amount of added sugars added to the food during the processing of the food, and if packaged as a separate ingredient, as packaged (whether as part of a package containing one or more ingredients or packaged as a single ingredient) to verify the amount of added sugars

present in the food (§ 101.9(g)(10)(iv)). (See section II.N for more details about this requirement.)

i. Reactions during processing. Sugars in some foods may undergo chemical changes mediated by chemical reactions from non-enzymatic browning (i.e., Maillard reactions and caramelization) and fermentation during food processing. During these reactions, some sugars are metabolized or otherwise transformed and converted into compounds that are no longer recognizable or detectable as sugars through conventional analytical methods (Ref. 77). We expect that the amount of added sugars transformed during non-enzymatic browning reactions is insignificant relative to the initial levels of sugars (Ref. 78).

Unlike browning reactions, fermentation is a process that typically involves the action of desirable microorganisms (e.g., yeasts and lactic acid bacteria) and enzymes to convert organic compounds, especially sugars and other carbohydrates, to simpler compounds such as carbon dioxide, lactic acid, and ethyl alcohol (Refs. 52 and 79). Typical foods that are subject to fermentation during manufacturing are breads, cheese, yogurt, vinegar, vegetables, meats, beer and wine. Some foods, such as sweetened, yeast-leavened breads and wines that are processed through a fermentation step contain added sugars which will likely be consumed by the microorganisms during fermentation; other foods processed through a fermentation step contain added sugars that will likely not be consumed to a large extent, if at all, during fermentation, for example, yogurt sweetened with sucrose. In addition, many products processed through a fermentation step, such as cheese, do not contain added sugars to aid in fermentation or improve taste (Ref. 78). Therefore, we tentatively conclude that the amount of added sugars present in foods prior to undergoing fermentation, with the exception of yeast-leavened bakery products, wines with less than 7 percent alcohol by volume, and beers that do not meet the definition of a

"malt beverage" as defined by the Federal Alcohol Administration Act (27 U.S.C. 211(a)(7)) with sugars added during the fermentation process, will not be significantly affected by virtue of the food having undergone fermentation. We do not have adequate information to assess the degradation of added sugars during fermentation for yeast-leavened bakery products, wine with less than 7 percent alcohol by volume, and beers that do not meet the definition of a malt beverage with sugars added before or during the fermentation process. (Ref. 78).

We request comments, including available data and information, on our tentative conclusions with respect to added sugars in products that are subjected to non-enzymatic browning reactions and fermentation. We specifically request data on the amount of variability that occurs among various types of products where added sugars are transformed into other compounds as a result of chemical reactions during food processing.

ii. Records required to assess compliance. For yeast-leavened bakery products, wines with less than 7 percent alcohol by volume, and beers that do not meet the definition of a malt beverage with sugars added before and during the fermentation process, it is unclear to us whether, as with most fermented foods, the reduction in the amount of added sugars would be insignificant. In addition to the records we propose to require for added sugars in foods generally, under proposed § 101.9(g)(10), we recognize that there is a need to consider other types of records related to added sugars content for a yeast-leavened bakery product, wine with less than 7 percent alcohol by volume, or a beer that does not meet the definition of a malt beverage when sugars are added to the food before or during the fermentation process (e.g. the added sugars are present during fermentation and the amount may be reduced by the fermentation process). Because of the unique issues that may be associated with a yeast-leavened bakery product, wine with less than 7 percent alcohol by volume, or a beer that does not meet the

definition of a malt beverage when added sugars are present during the fermentation process (Ref. 78), we are proposing a new subparagraph (§ 101.9(g)(10)(v)) to specifically address records requirements for these products.

Some manufacturers of yeast-leavened bakery products, wine with less than 7 percent alcohol by volume, and beers that do not meet the definition of a malt beverage where sugar is added before or during the fermentation process would likely have more detailed information about the reduction in added sugars from the process for the products they manufacture. Thus, we anticipate that manufacturers of some of these foods that undergo fermentation would be able to determine the amount of added sugars in the finished food product. For example, manufacturers could choose to determine through laboratory analysis the amount of added sugars as well as naturally occurring sugars consumed in their product during the fermentation process. Other manufacturers that are unable to conduct additional laboratory analyses of their product may rely on a scientific document (e.g., journal article or reference book) showing the amount of added sugars typically consumed during fermentation in a specific food product (see proposed § 101.9(g)(10)(v)(A)). Manufacturers may use information gathered through additional analyses or from scientific references to adjust the amount of sugars added in processing to achieve the desired taste and organoleptic properties in the finished food product.

We also recognize that some manufacturers of these foods may not be able to use scientific data and information to verify the amount of added sugars in the finished food product. We tentatively conclude that it is appropriate to include, as an alternative to the use of scientific data and information for such verification, proposed record requirements for the amount of added sugars added to these products before and during fermentation for the verification of the declaration of added sugars content (see proposed § 101.9(g)(10)(v)(B)). As with other products

containing added sugars, the amount of sugars added before or during fermentation could be determined through information such as databases, recipes, formulations, or batch records.

Therefore, we are proposing, in § 101.9(g)(10)(v), to require a manufacturer of yeast-leavened bakery products, wines with less than 7 percent alcohol by volume, and beers that do not meet the definition of a malt beverage with sugars added before and during the fermentation process to make and keep records of added sugars necessary to determine the amount of added sugars present in the finished food in one of two ways. The first would require the manufacturer to make and keep records of all relevant scientific data and information relied upon by the manufacturer that demonstrates the amount of added sugars in the food after fermentation and a narrative explaining why the data and information are sufficient to demonstrate the amount of added sugars declared in the finished food. When the manufacturer is relying upon scientific data and information from reference documents to determine the amount of added sugars in these finished food products, the information used must be specific to the type of fermented food manufactured. For example, if a manufacturer produces raisin bread, the reference that the manufacturer is relying upon would need to show the amount of sugars typically consumed in raisin bread that undergoes fermentation. The second would require the manufacturer to make and keep records of the amount of added sugars added to the food before and during the processing of the food, and, if packaged as a separate ingredient, as packaged (whether as part of a package containing one or more ingredients or packaged as a single ingredient). The records would need to be made available to FDA consistent with the proposed requirements in § 101.9(g)(11).

It is likely that the actual amount of added sugars remaining in yeast-leavened breads, wines with less than 7 percent alcohol by volume, and beers that do not meet the definition of a

malt beverage after they undergo fermentation will be less than the amount added before processing. We are proposing in section II.N to allow for reasonable deficiencies of added sugars under labeled amounts that are acceptable within current good manufacturing practice in § 101.9(g)(6). Because the consumer is not generally harmed if the amount declared on the nutrition label is a reasonable overage of the actual amount as indicated by § 101.9(g)(6), when the manufacturer chooses, as the declaration, the amount of sugars added to these specific foods before fermentation, then we consider the actual amount of added sugars in the finished food product to be a reasonable deficiency under § 101.9(g)(6). In some cases of these specific fermented foods, when the amount of sugar added to a product before fermentation is declared, it will exceed the amount of total sugars in the finished food product determined through laboratory analysis. This is due to the fact that the amount of added sugars consumed during the fermentation process is not reflected in the declared amount. In such cases, we tentatively conclude that it may be confusing to the consumer if the amount of added sugars declared exceeds the amount of total sugars declared on the Nutrition Facts label. Therefore, we are proposing in § 101.9(g)(10)(v)(B) that the amount of added sugars declared shall not exceed the amount of total sugars declared on the label.

#### 4. Sugar Alcohols

FDA regulations define sugar alcohols, in part, as the sum of saccharide derivatives in which a hydroxyl group replaces a ketone or aldehyde group (e.g., mannitol or sorbitol) (§ 101.9(c)(6)(iii)).

a. Voluntary Declaration--FDA regulations permit the voluntary declaration of sugar alcohols on the Nutrition Facts label (§ 101.9(c)(6)(iii)). In 2005, we received a citizen petition from the Sugar Association (Docket No. 2005-P-0373) requesting, among other requests,

mandatory declaration of sugar alcohols on the Nutrition Facts label

(<http://www.regulations.gov/#!docketDetail;D=FDA-2005-P-0373>). The petition stated that, without this information, consumers would be misinformed about important modifications to foods and cannot make informed decisions about their particular sensitivity to the potential effects of sugar alcohols on the body. In the 2007 ANPRM, we asked whether the declaration of sugar alcohols should continue to be voluntary or made mandatory. We considered comments received (Ref. 47) as well as arguments presented by the petition.

We tentatively conclude that declaration of sugar alcohols should continue to be voluntary. Although a quantitative intake recommendation for sugar alcohols is not available from relevant U. S. consensus reports, sugar alcohols have positive health effects when they replace sugars in the diet. For example, there is well-established evidence to indicate that replacing sugars in the diet with sugar alcohols reduces the risk of dental caries, including the evidence used to support the health claims authorized by FDA on sugar alcohols and dental caries (72 FR 52783 at 52785; § 101.80). Therefore, we tentatively conclude that sugar alcohols have public health significance and, in the absence of a quantitative intake recommendation, voluntary declaration is consistent with the factors we consider for when voluntary declaration is appropriate (section I.C.). Accordingly, we are proposing to continue to provide for the voluntary declaration of sugar alcohols (in § 101.9(c)(6)(iii) redesignated as § 101.9(c)(6)(iv)).

We disagree with the petition that mandatory declaration of sugar alcohols is necessary to ensure that consumers are not misinformed about modifications to foods. Sugar alcohols that are added to food must be listed in the ingredients list on food labels and, therefore, consumers will be informed of their use in a product. We also disagree with the comment that supported mandatory declaration when there is at least 1 gram of sugar alcohols per serving due to

gastrointestinal problems at such a level. As warranted, FDA regulations require specific labeling statements to accompany the use of certain sugar alcohols to provide information to consumers about any gastrointestinal effects. For example, in the case of mannitol and sorbitol, the statement "Excessive consumption may have a laxative effect," is required on the label and labeling of a food whose reasonably foreseeable consumption may result in a daily ingestion of 20 g for mannitol (21 CFR 180.25) and 50 g for sorbitol (§ 184.1835 (21 CFR 184.1835)).

b. Use of the Term "Sugar Alcohol"--In 1995, we received a citizen petition submitted by the Calorie Control Council requesting the use of the term "polyols" in lieu of "sugar alcohols" (Docket No. FDA-1995-P-0142) (<http://www.regulations.gov/#!docketDetail;D=FDA-1995-P-0142>). The petition stated that "polyol" is a regulatory term used in other countries, such as Canada and New Zealand. In addition, the petition cited a survey that showed that 78 percent of consumers surveyed thought that products with sugar alcohol contained some sugar even when labeled "sugar free" and 69 percent thought that the product contained some alcohol. We considered the petition as well as comments in response to the 2007 ANPRM (Ref. 80).

We previously considered the use of "polyol" (a contraction of "polyalcohol") and determined that it could be potentially more confusing to consumers than the term "sugar alcohol." However, we acknowledge that consumers also may not be familiar with the term "sugar alcohol." Therefore, in § 101.9(c)(6)(iii), we allow for the use of the name of the specific sugar alcohol in lieu of "sugar alcohols," provided that only one sugar alcohol is present in the food, since many of the sugar alcohols are listed as ingredients (e.g., sorbitol, mannitol, xylitol) and hence may be more recognizable for consumers (58 FR 2079 at 2100).

We continue to support the term "sugar alcohols" rather than "polyols," because "sugar alcohols" more accurately describes the group of substances encompassed in the definition in

§ 101.9(c)(6)(iii). "Polyols" includes non-carbohydrate polyalcohols, such as polyesters, whereas "sugar alcohols," as defined by FDA, includes only carbohydrates. Accordingly, we are not proposing to change the term "sugar alcohols" when used on the Nutrition Facts label, as specified in § 101.9(c)(6)(iii) redesignated as § 101.9(c)(6)(iv).

c. DRV--FDA regulations do not provide a DRV for total sugar alcohols or for individual sugar alcohols. A quantitative reference intake recommendation for sugar alcohols is not available from current consensus reports and we have no basis on which to consider setting an appropriate DRV. Therefore, we are not proposing to set a DRV for sugar alcohols.

d. Caloric Value--The caloric value for carbohydrates, other than insoluble fiber, is 4 kcal/g (§ 101.9(c)(1)(i)(C)). Sugar alcohols have been shown to have a caloric value lower than 4 kcal/g (Refs. 81 and 82). The 2007 ANPRM asked for comment on (1) how the energy contribution of sugar alcohols should be represented on the label since energy values vary, and (2) what analytical methods could be used to determine the energy contribution of sugar alcohols. We considered comments received (Ref. 47). We also considered relevant caloric values recommended by the Life Sciences Research Office (LSRO) that were determined by various methods, including studies conducted in animals and human subjects, and based on the amount of energy metabolized or net energy values (Refs. 81 and 82). LSRO expert panel reports provided the following caloric values for individual sugar alcohols: Isomalt (2.0 kcal/g), lactitol (2.0 kcal/g), xylitol (2.4 kcal/g), maltitol (2.1 kcal/g), sorbitol (2.6 kcal/g), hydrogenated starch hydrolysates (3.0 kcal/g), and mannitol (1.6 kcal/g).

We support the use of the LSRO caloric values for individual sugar alcohols. The LSRO reports used appropriate methods and study design criteria for measuring caloric value, and noted that human data were preferred and that animal data should be viewed as supplemental

information. We do not have any data that would question the caloric values determined by the LSRO reports for the specified sugar alcohols. We did not identify any human studies published since the release of the LSRO reports that demonstrate that a different caloric value for any of these sugar alcohols would be more appropriate. Therefore, we are proposing to amend § 101.9(c)(1)(i)(F) to establish the following general factors for caloric values of sugar alcohols, using the values recommended by LSRO: Isomalt - 2.0 kcal/g, lactitol - 2.0 kcal/g, xylitol - 2.4 kcal/g, maltitol - 2.1 kcal/g, sorbitol - 2.6 kcal/g, hydrogenated starch hydrolysates - 3.0 kcal/g, and mannitol - 1.6 kcal/g. Accordingly, we are also proposing to amend § 101.9(c)(1)(i)(C) such that the 4 kcal/g is not applied to sugar alcohols.

## 5. Dietary Fiber

### a. Dietary Fiber

i. Definition. FDA regulations do not establish a definition for dietary fiber. There is no specific chemical definition for dietary fiber. Because of the difficulties in accurately isolating the set of fibers relevant to health, in 2001, the IOM established a panel to develop a new definition of dietary fiber (IOM Panel on the Definition of Dietary Fiber or IOM Panel). Subsequently, the IOM then issued a report defining "total fiber" as the sum of "dietary fiber" and "added fiber," where "dietary fiber" consists of non-digestible carbohydrates and lignin that are intrinsic and intact in plants, and "added fiber" (referred to as "functional fiber" in the IOM Macronutrient Report) consists of isolated, non-digestible carbohydrates that have beneficial physiological effects in humans (Ref. 24). The IOM's definitions of "dietary fiber" and "total fiber" only include those fibers that are considered to have health benefits. The 2007 ANPRM asked for public comment on whether the IOM dietary or functional fiber definitions should become the FDA definition for dietary fiber. We also asked whether it should develop criteria

for identifying fibers that demonstrate a physiological benefit, and, if so, what those criteria should be. We received several comments (Ref. 47).

We considered IOM recommendations, comments received, and relevant international guidelines. The Codex Alimentarius Commission adopted the following definition of dietary fiber in 2010 (Ref. 67):

"Dietary fibre means carbohydrate polymers<sup>1</sup> with ten or more monomeric units,<sup>2</sup> which are not hydrolysed by the endogenous enzymes in the small intestine of humans and belong to the following categories:

- Edible carbohydrate polymers naturally occurring in the food as consumed,
- carbohydrate polymers, which have been obtained from food raw material by physical, enzymatic or chemical means and which have been shown to have a physiological effect of benefit to health as demonstrated by generally accepted scientific evidence to competent authorities, and
- synthetic carbohydrate polymers which have been shown to have a physiological effect of benefit to health as demonstrated by generally accepted scientific evidence to competent authorities.

As with the IOM definition of "total fiber," the 2010 Codex definition for "dietary fiber" includes naturally occurring fibers and only those non-digestible carbohydrates added to food that have a physiological effect that is beneficial to human health.

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<sup>1</sup> "When derived from a plant origin, dietary fibre may include fractions of lignin and/or other compounds associated with polysaccharides in the plant cell walls. These compounds also may be measured by certain analytical method(s) for dietary fibre. However, such compounds are not included in the definition of dietary fibre if extracted and re-introduced into a food." (Ref. 67).

<sup>2</sup> "Decision on whether to include carbohydrates from 3 to 9 monomeric units should be left to national authorities." (Ref. 67).

Dietary fiber represents a heterogeneous group of compounds that vary in their carbohydrate composition, linkages between carbohydrates, and molecular weight. As stated previously, there is no specific chemical definition for dietary fiber. Therefore, considering the IOM and Codex definitions and comments received, as well as the role of the dietary fiber declaration on the Nutrition Facts label, we tentatively conclude that a regulatory definition for dietary fiber should be one that emphasizes its physiological effect that is beneficial to human health. The declaration of dietary fiber that accurately reflects the amount of fiber that provides a physiological effect that is beneficial to human health would assist consumers in maintaining healthy dietary practices.

We are proposing a single definition for dietary fiber that is equivalent to the IOM's definition for "total fiber," rather than IOM's separate definitions of "dietary fiber" and "functional fiber." Because both "dietary fiber" and "functional fiber" as defined by IOM are considered to have beneficial health effects, we tentatively conclude that there is little benefit for consumers in distinguishing between these two types of fiber on the Nutrition Facts label. In addition, the IOM itself recognized analytical limitations in distinguishing between "dietary fiber" and "functional fiber" and noted that the labeling of "total fiber" would be more practical than labeling "dietary fiber" and "functional fiber" separately (Ref. 24).

The Codex definition includes a minimum degree of polymerization (DP) for a carbohydrate of 10, and it also provides that the inclusion of non-digestible carbohydrates with 3 to 9 monomeric units should be left to national authorities. The IOM's definition for "total fiber" includes those non-digestible carbohydrates of 3 to 9 DP (Ref. 24).

Because we seek to include in our definition non-digestible carbohydrates with physiological effects that are beneficial to human health, regardless of size, we are proposing to adopt a definition for total fiber that includes a DP of  $\geq 3$ , consistent with the IOM's definition.

Therefore, we are proposing to amend § 101.9(c)(6)(i) to include the following definition for dietary fiber: (1) Non-digestible soluble and insoluble carbohydrates (with 3 or more monomeric units) and lignin that are intrinsic and intact in plants; (2) isolated and synthetic non-digestible carbohydrates (with 3 or more monomeric units) that FDA has granted be included in the definition of dietary fiber, in response to a petition submitted to FDA under § 10.30 (21 CFR 10.30) demonstrating that such carbohydrates have a physiological effect(s) that is beneficial to human health; or (3) isolated and synthetic non-digestible carbohydrates (with 3 or more monomeric units) that are the subject of an authorized health claim. We invite comment on the proposed definition of dietary fiber.

As proposed, under provisions 2 and 3, manufacturers would be required to provide evidence to FDA to demonstrate the physiological effects that are beneficial to human health, of isolated and synthetic non-digestible carbohydrates added to food, and FDA would have to grant a petition or authorize a health claim before they can be considered as "dietary fiber" for declaration on the Nutrition Facts label. Manufacturers would use the citizen petition process in § 10.30 or, in case of a related health claim, the health claims petition process in § 101.70. We intend to issue guidance to industry on submissions to demonstrate physiological effects that are beneficial to human health.

Under these proposed provisions, both  $\beta$ -glucan soluble fiber (§ 101.81(c)(2)(ii)(A)) and barley  $\beta$ -fiber (§ 101.81(c)(2)(ii)(A)(6)) that are added to foods would meet the definition of dietary fiber and, therefore, would be included in the amount of dietary fiber declared on the

Nutrition Facts label. We are proposing to list isolated and synthetic non-digestible carbohydrates that have been determined by FDA to have a physiological effect that is beneficial to human health, in § 101.9(c)(6)(i). Accordingly, we are proposing to amend § 101.9(c)(6)(i) to list  $\beta$ -glucan soluble fiber and barley  $\beta$ -fiber (as these substances are described in § 101.81(c)(2)(ii)(A) and (c)(2)(ii)(A)(6), respectively) as isolated and synthetic non-digestible carbohydrates that have been determined by FDA to have a physiological effect that is beneficial to human health and, therefore, must be included in the declaration of dietary fiber. Under this process, we would amend § 101.9(c)(6)(i) to list any additional isolated and synthetic non-digestible carbohydrates that FDA determines have a physiological effect that is beneficial to human health, through either the citizen petition process or the health claims petition process.

ii. Mandatory declaration. Section 403(q)(1)(D) of the FD&C Act specifies, in part, that for each serving size or other unit of measure of a food, the amount of dietary fiber must be provided. Accordingly, FDA regulations require the declaration of dietary fiber on the Nutrition Facts label, as provided in § 101.9(c)(6)(i).

We did not ask any questions about the mandatory labeling of dietary fiber in the 2007 ANPRM, and we received no comments on this subject. Dietary fiber is not an essential nutrient. However, it has physiological effects that are beneficial to human health, such as attenuation of postprandial blood glucose concentrations, attenuation of blood cholesterol concentrations, and improved laxation (Ref. 66). The IOM DRI report noted that consumption of certain dietary fibers, particularly those that are poorly fermented (i.e., insoluble fiber), improve fecal bulk and laxation and ameliorate constipation (Ref. 66). In addition, soluble fiber plays a beneficial role in reducing the risk of heart disease (Ref. 66). "Dietary fiber" is identified as a nutrient of public health concern in the 2010 DGA. The 2010 DGA also emphasized the

consumption of whole grains, in part, because they are a source of dietary fiber, noting that choosing whole grains that are higher in dietary fiber has health benefits in addition to meeting nutrient needs (Ref. 6).

Given the health benefits of dietary fiber, we have no basis to conclude that the declaration of dietary fiber is no longer necessary to assist consumers in maintaining healthy dietary practices. Therefore, we are not proposing to change our current requirement for the mandatory declaration of dietary fiber in § 101.9(6)(i).

With respect to the term used to declare dietary fiber content on the Nutrition Facts label, we considered comments received in response to the 2007 ANPRM (Ref. 47). The term "dietary fiber" has been listed on the Nutrition Facts label since 1993. One survey pointed out by comments suggests that both "fiber" and "dietary fiber" are similarly acceptable by consumers (Ref. 47). Alternative terms such as "natural fiber" or "isolated fiber" would not be appropriate to declare all dietary fiber given that we are proposing a definition of dietary fiber that includes both natural fiber and fiber that is added to food. Although the IOM used the term "total fiber," there is no evidence to suggest that this term is preferable to the term "dietary fiber." Therefore, we are not proposing to change the current requirement to declare dietary fiber using the term "dietary fiber," as specified in § 101.9(f). However, we request comment on this issue, including consumer understanding of the term "dietary fiber" relative to other relevant terms.

iii. Analytical methods. Per FDA regulations, compliance with the requirement for declaration of dietary fiber is determined using appropriate AOAC analytical methods (58 FR 2079 at 2113; § 101.9(g)(2)). In the 2007 ANPRM, we noted the IOM Panel's consideration of analytical issues related to dietary fiber, and asked whether we should continue to use the AOAC

International methods to determine the amount of dietary fiber and, if not, what other or additional methods should be used.

We reviewed comments (Ref. 47) received as well as current AOAC methods for dietary fiber and the various analytes measured by these methods in light of our proposed definition for dietary fiber. AOAC methods, such as AOAC 985.29, 991.43 and 994.13, measure soluble and insoluble polysaccharides, lignin, higher molecular weight non-digestible oligosaccharides (DP > 12), and some resistant starch, inulin and low molecular weight non-digestible oligosaccharides (DP < 10). These methods do not measure all non-digestible carbohydrates with a DP < 10. In contrast, newer methods (AOAC 2009.01 and AOAC 2011.25) measure all low molecular weight non-digestible carbohydrates (i.e., non-digestible oligosaccharides) in addition to the higher molecular weight non-digestible carbohydrates (Ref. 83). Thus, these newer, more inclusive AOAC methods would be more consistent with our proposed definition. However, there is no analytical method that can distinguish non-digestible carbohydrates that have a beneficial physiological effect from those that do not.

We are proposing to amend § 101.9(c)(6)(i) to indicate that dietary fiber content may be determined by subtracting the amount of non-digestible carbohydrates added during processing that do not meet the definition of dietary fiber (in proposed § 101.9(c)(6)(i)) from the value obtained using AOAC 2009.01, AOAC 2011.25 or an equivalent AOAC method of analysis as given in the "Official Methods of Analysis of the AOAC International" 19th Edition. If a product contains only non-digestible carbohydrates that meet the proposed definition of dietary fiber, using AOAC 2009.01, AOAC 2011.25, or an equivalent method would be sufficient to quantify the dietary fiber content of a food. However, if the product contains both dietary fiber that is included in the proposed definition (e.g., naturally occurring fibers) and non-digestible

carbohydrates not included in the definition (e.g., synthetic fibers without a physiological effect that is beneficial to human health), neither AOAC 2009.01 or AOAC 2011.25 nor an equivalent AOAC method would accurately quantify the dietary fiber that could be declared on the Nutrition Facts label, because the determination of fiber by these methods would include the non-digestible carbohydrates that do not meet the proposed definition of dietary fiber.

To verify that the quantity of dietary fiber declared on the Nutrition Facts label includes only those fibers that meet the regulatory definition of dietary fiber, when a food contains a mixture of non-digestible carbohydrates that meet the proposed dietary fiber definition and those that do not, we are proposing in § 101.9(c)(6) and (g)(10) to require manufacturers to make and keep written records to verify the amount of added non-digestible carbohydrates that do not meet the proposed definition of dietary fiber. See discussion in section II.N. Such records would provide information to verify that the amount of dietary fiber declared meets the proposed definition. The amount of non-digestible carbohydrate measured by AOAC 2009.01 or AOAC 2011.25 (or an equivalent AOAC method) minus the amount of added non-digestible carbohydrate that has not been determined by FDA to have a physiological effect that is beneficial to human health would reflect the amount of dietary fiber lawfully declared on the label.

iv. DRV. The DRV for dietary fiber is 25g (§ 101.9(c)(9)). We did not ask specific questions in the 2007 ANPRM and received no comments on the DRV for dietary fiber. In 2002, the IOM set an AI of 14 g/1,000 kcal for "total fiber" (Ref. 66). The AI was primarily based on the intake level that was associated with the greatest reduction in the risk of CHD. We are proposing to define dietary fiber to include those fibers that have a physiological effect that is

beneficial to human health (see section II.D.5.) and, as such, the AI for "total fiber" provides an appropriate basis for setting a DRV for dietary fiber declared on the Nutrition Facts label.

Therefore, we are proposing to use 14 g/1,000 kcal as the basis for a DRV for dietary fiber. Using a reference calorie intake of 2,000 calories (see section II.A.3.), we are proposing to amend § 101.9(c)(9) to set a DRV of 28 g ( $14\text{g}/1,000\text{ kcal} \times 2,000\text{ kcal/d}$ ) for dietary fiber.

b. Soluble and Insoluble Fiber--Dietary fibers can be classified as being soluble or insoluble. Soluble fibers, such as pectin and gums, dissolve in water and are digested by the bacteria in the large intestine. Insoluble fibers, such as cellulose and lignin, do not dissolve in water and are not digested by bacteria in the large intestine, adding bulk to the stool for improved laxation.

i. Definition. Like dietary fiber, FDA regulations do not establish definitions for soluble or insoluble fiber. The 2007 ANPRM did not ask questions about definitions for soluble and insoluble fiber and we did not receive any comments about them. Because soluble and insoluble fibers are components of dietary fiber, we tentatively conclude that soluble and insoluble fibers must meet the proposed definition of dietary fiber. Therefore, we are proposing in § 101.9(c)(6)(i)(A) and (c)(6)(i)(B) that soluble fiber and insoluble fiber, respectively, must meet the definition of dietary fiber in paragraph 101.9(c)(6)(i).

ii. Voluntary declaration. FDA regulations permit, but do not require, the declaration of soluble fiber (§ 101.9(c)(6)(i)(A)) and insoluble fiber (§ 101.9(c)(6)(i)(B)) on the Nutrition Facts label. In the 2007 ANPRM, FDA asked whether the declaration of soluble and insoluble fiber should continue to be voluntary or made mandatory. We considered comments received (Ref. 47).

While a quantitative intake recommendation is not available from relevant U. S. consensus reports, there is well-established evidence showing that soluble and insoluble fibers have distinct physiological effects that are beneficial to human health. For example, the IOM noted that the body of evidence indicates that non-fermentable fiber sources (often isolated as insoluble fiber) promote laxation, and improved laxation is an established physiological effect that is beneficial to human health (Ref. 66). Therefore, we tentatively conclude that soluble and insoluble fibers that meet the definition of dietary fiber have public health significance and, in the absence of quantitative intake recommendations, are consistent with the considerations for voluntary declaration explained in section I.C. Accordingly, we are proposing to continue to provide for the voluntary declaration of soluble and insoluble fibers, as specified in § 101.9(c)(6)(i)(A) and (B).

With respect to the term used to declare dietary fiber content on the Nutrition Facts label, in 2001, the IOM Panel recommended that the terms "soluble" and "insoluble" fiber be phased out and replaced with relevant descriptors of the physicochemical properties of particular fibers (e.g., "viscous" or "fermentable" fiber to replace "soluble" fiber), as the characterization of the properties of various fibers becomes standardized (Ref. 24). In the 2007 ANPRM, we noted this recommendation and asked for public comment on whether the terms "soluble fiber" and "insoluble fiber" should be changed to "viscous" and "nonviscous" fiber.

We considered the IOM recommendations as well as comments received (Ref. 47), and tentatively conclude that the terms "soluble fiber" and "insoluble fiber" are most appropriate for reasons discussed in this document. While the IOM recommended replacing "soluble fiber" and "insoluble fiber" with appropriate physicochemical terms as the characterization of the properties of various fibers becomes standardized, such standardization has not yet occurred. In addition,

as the comments stated, viscosity does not predict fermentability (Ref. 47), which the IOM recognized is a physicochemical property that is linked to health benefits, and it is not known at what level of viscosity a fiber begins to have a physiological effect (Ref. 66). Moreover, there are no currently available scientifically valid methods that FDA could use to measure the amount of various fibers defined by their physicochemical properties in various food matrices, whereas scientifically valid methods to measure soluble and insoluble fiber are currently available. Therefore, we are not proposing any changes to the use of terms "soluble fiber" and "insoluble fiber" in the Nutrition Facts label.

iii. Analytical methods. Per FDA regulations, compliance with any declaration of soluble or insoluble fibers is determined using appropriate AOAC analytical methods (§ 101.9(g)(2)). While there are a number of traditional AOAC methods available for measuring soluble fiber (e.g., AOAC 991.43 and 993.19) and insoluble fiber (e.g., AOAC 991.42 and 991.43), as is the case with dietary fiber, these methods cannot measure all non-digestible carbohydrates with a DP < 10. A newer method, AOAC 2011.25 (Ref. 83), can measure low molecular weight non-digestible carbohydrates, as well as separately measure soluble and insoluble non-digestible carbohydrates. However, as in the case of AOAC 2009.01, AOAC 2011.25 (Ref. 83) cannot distinguish soluble and insoluble non-digestible carbohydrates that have a physiological effect that is beneficial to human health from those that do not.

We are proposing to amend § 101.9(c)(6)(i)(A) and (c)(6)(i)(B) to indicate that the soluble and insoluble non-digestible carbohydrate content may be calculated by first using AOAC 2011.25, or an equivalent AOAC method of analysis. If a food contains only non-digestible carbohydrates that meet the proposed definition of dietary fiber (e.g., contains naturally occurring fiber only), then AOAC 2011.25 or an equivalent AOAC method would

measure the amount of soluble or insoluble fiber that can be declared on the Nutrition Facts label. If a food contains a mixture of non-digestible carbohydrates that do and do not meet the proposed dietary fiber definition, and the label of the food declares soluble or insoluble fiber content, we are proposing to amend § 101.9(c)(6)(i)(A) and (c)(6)(i)(B) to require manufacturers to make and keep records to verify the amount of soluble or insoluble non-digestible carbohydrates that do not meet the proposed definition of dietary fiber that have been added to the food product during processing. (See discussion in section II.N.)

iv. DRV. FDA regulations do not establish DRVs for soluble fiber or insoluble fiber. No DRIs were established for soluble or insoluble fiber during the IOM's evaluation of a DRI for dietary fiber (Ref. 66), and we have no basis on which to derive an appropriate DRV. Therefore, we are not proposing to set a DRV for either soluble fiber or insoluble fiber.

v. Caloric value. Per FDA regulations, the caloric content of a food may be calculated by, among other methods, using the general factors of 4, 4, and 9 kcal/g for protein, total carbohydrate less the amount of insoluble dietary fiber, and total fat, respectively (§ 101.9(c)(1)(i)(C)). Accordingly, soluble fiber, which is encompassed within "total carbohydrate," is assigned a general factor of 4 kcal/g. We did not ask questions about the caloric value of dietary fibers in the 2007 ANPRM, but received a few comments on the caloric value of soluble fiber, including that 4 kcal/g for soluble fiber was too high and that we should consider 2 kcal/g, which is the caloric value identified by the United Nations Food and Agriculture Organization. We also received a citizen petition from the Calorie Control Council requesting that the caloric value of soluble fiber be no more than 2 kcal/g (Docket No. FDA-1997-P-0232), based on the caloric contribution of energy yielding short chain fatty acids that

are produced as a result of colonic fermentation of soluble fiber

(<http://www.regulations.gov/#!docketDetail;D=FDA-1997-P-0232>).

We agree with the comments and the petition supporting a caloric value of 2 kcal/g for soluble fiber. The anaerobic fermentation of soluble fibers in the colon has been shown to yield less energy than the 4 kcal/g obtained from aerobic metabolism of carbohydrates (Ref. 66). In addition, the absorption of energy yielding short chain fatty acids that are produced as a result of colonic fermentation of soluble fiber can vary, and data indicate that the average energy yield from soluble fibers is 1.5 to 2.5 kcal/g (Ref. 66). Therefore, we tentatively conclude that 2 kcal/g is a reasonable estimate of the caloric value of soluble non-digestible carbohydrates.

Accordingly, we are proposing to amend § 101.9(c)(1)(i)(C) to establish a general factor of 2 kcal/g as the caloric value of soluble non-digestible carbohydrates. Insoluble non-digestible carbohydrates are not included in the caloric calculation.

We are also proposing a corresponding change to the introductory text in § 101.9(c)(1)(i)(C) to exclude non-digestible carbohydrate from total carbohydrate. FDA regulations require that the calories from total carbohydrate be calculated by using the general factor of 4 kcal/g of carbohydrate less the amount of insoluble dietary fiber (§ 101.9(c)(1)(i)(C)). We are proposing a new definition of dietary fiber (see section II.D.5.a.i.) that only allows for the declaration of dietary fibers that are added to foods that we have determined to have a physiological effect that is beneficial to human health, as "dietary fiber" on the Nutrition Facts label. Therefore, the proposed new definition of dietary fiber would exclude soluble and insoluble non-digestible carbohydrates that do not meet the proposed definition of dietary fiber. For the purposes of calculating calories from soluble non-digestible carbohydrate, the proposed factor of 2 kcal/g should apply to those soluble non-digestible carbohydrates that both do and do

not meet the proposed definition of dietary fiber. To ensure that soluble non-digestible carbohydrates that do and do not meet the proposed definition of dietary fiber are excluded from total carbohydrate, such that a general factor of 2 kcal/g is applied to these non-digestible carbohydrates, we are proposing to amend § 101.9(c)(1)(i)(C) to require that calories from carbohydrate be calculated using a general factor of 4 kcal/g of total carbohydrate less the amount of non-digestible carbohydrates, which includes soluble and insoluble non-digestible carbohydrates that do and do not meet the definition of dietary fiber (see also section II.D.1.f.).

#### 6. Other Carbohydrate

FDA regulations define "other carbohydrate" as the difference between total carbohydrate and the sum of dietary fiber, sugars, and sugar alcohol, except that if sugar alcohol is not declared, "other carbohydrate" is defined as the difference between total carbohydrate and the sum of dietary fiber and sugars (§ 101.9(c)(6)(iv)). Examples of "other carbohydrate" include starch and oligosaccharides. A statement of the amount of "other carbohydrate" may be voluntarily declared on the Nutrition Facts label (§ 101.9(c)(6)(iv)). We did not ask questions about the labeling of "other carbohydrate" in the 2007 ANPRM, and we received no comments on this issue. However, we reconsidered the provision for voluntary declaration of "Other carbohydrate" on the Nutrition Facts label based on the factors we consider for the mandatory and voluntary declaration discussed in section I.C.

"Other carbohydrate" represents different types of carbohydrate, and, unlike sugars and dietary fiber, carbohydrates covered under this heterogeneous category have no shared physiological effects. Moreover, there is no well-established evidence to support the role of particular types of carbohydrate that fall within the "other carbohydrate" category, such as starch and oligosaccharides, in human health that is based on reliable and valid physiological or clinical

endpoints. In addition, a quantitative intake recommendation for "Other carbohydrate" is not available from relevant consensus reports. Given the lack of public health significance or a quantitative intake recommendation for "other carbohydrate" as a category, consistent with the factors discussed in section I.C., we tentatively conclude that "Other carbohydrate" should no longer be permitted to be declared on the Nutrition Facts label.

Therefore, we are proposing to remove current § 101.9(c)(6)(iv) to remove the provision that allows for the voluntary declaration of "Other carbohydrate" on the Nutrition Facts label. We are also proposing to make a corresponding revision to § 101.9(g)(4) and (g)(6) to remove references to "Other carbohydrates." We invite comment on this issue, including any other data or factual information that we should consider in making a final determination.

### E. Protein

#### 1. Mandatory and Voluntary Declaration

Section 403(q)(1)(D) of the FD&C Act requires food labeling to bear nutrition information about protein. FDA regulations require the declaration of the amount of protein by weight, and provide for voluntary declaration of the percent DV for protein on the Nutrition Facts label (§ 101.9(c)(7)(i)). In response to the 2007 ANPRM, one comment supported the current approach, whereas another comment recommended that FDA require the labeling of the percent DV for protein.

We considered current scientific evidence and comments received (Ref. 47). There is strong evidence based on valid physiological and clinical endpoints that protein is an essential nutrient that is necessary for human health and growth (Refs. 6 and 84). Therefore, we tentatively conclude that the declaration of protein content remains necessary to assist consumers in maintaining healthy dietary practices. In addition, because protein intake in the U. S.

population continues to be adequate when compared to the EAR absent a mandatory percent DV declaration (Ref. 85), we tentatively conclude that the declaration of protein as a percent DV should remain voluntary. Accordingly, we are not proposing any changes to the requirement for declaration of the quantitative amount of protein and the voluntary declaration of this amount as a percent DV on the Nutrition Facts label.

## 2. Analytical Methods

Under § 101.9(c)(7), protein may be calculated on the basis of 6.25 times the nitrogen content of the food determined by the appropriate method of analysis as given in the Official Methods of Analysis of AOAC International, 15th ed. (1990), except when the official procedure for a specific food requires another factor. On December 21, 2000, we received a citizen petition from Protein Technologies International, Inc. (FDA-2000-P-0569), requesting that FDA amend the reference to the method used to calculate protein content found in § 101.9(c)(7) to read "the appropriate method of analysis as given in the Official Methods of Analysis of the AOAC International, 17th ed. (2000)" (<http://www.regulations.gov/#!docketDetail;D=FDA-2000-P-0569>). The petition explained that the only approved method for use in human food in the 15th edition of the AOAC Official Methods of Analysis was the Kjeldahl method, which the petition stated involves the use of a mercury catalyst and, therefore, can be potentially harmful to humans and the environment. The petition asserted that the 17th edition of the AOAC Official Methods of Analysis recognized an alternative method, the Combustion method, also known as the Dumas method, to measure protein levels in some human foods and that we should permit its use for measuring protein content.

We note that not all Kjeldahl methods included in the Official Methods of Analysis of the AOAC contain a mercury catalyst. Furthermore, the Kjeldahl method is a well-recognized,

standard method for determination of protein content. In fact, it is the method cited for use in determination of protein digestibility in the "Protein Quality Evaluation, Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation" (Ref. 86) that is incorporated by reference in § 101.9(c)(7)(ii).

As discussed in section II.N.2., we see a need to update the version of the Official Methods of Analysis of the AOAC International that we use for compliance purposes because newer, and sometimes better, analytical methods for many nutrients are included in versions of the methods that have been published since the 15th edition. We are, therefore, proposing to amend § 101.9(c)(7) to incorporate by reference the Official Methods of Analysis of the AOAC International, 19th ed. (2012) by removing "15th Ed. (1990)" and adding in its place "19th Ed. (2012)." The 19th edition is the most recent edition of the published AOAC methods, and includes both the Kjeldahl and the Combustion/Dumas methods. While the petition requested that the Agency amend § 101.9(c)(7) to incorporate the 17th edition of the AOAC methods, the 19th edition includes all of the methods for protein that were available in the 17th edition. Thus, the proposed action is consistent with the petition's request. If a newer version of the Official Methods of Analysis of the AOAC International is published before publication of the final rule (assuming that this rulemaking does result in a final rule), we will consider, as appropriate, using the most recent version of the official AOAC methods in the final rule. To the extent that the methods for protein determination in the newer version differ from those provided in the 19th edition of the Official Methods of Analysis of the AOAC International, we will consider the need to seek additional public comment on the version of the AOAC Methods of Analysis of the AOAC International that is incorporated by reference in § 101.9(c)(7).

### 3. DRV

The DRV for protein is 50 g (§ 101.9(c)(9)) and represents 10 percent of the 2,000 reference calorie intake level. The IOM Labeling Committee considered the IOM's AMDR for protein (10 to 35 percent of energy intake for adults) and the AMDRs for fat and carbohydrates, and recommended setting the DV for protein based on the difference between total energy intake and the combined DVs for fat and carbohydrate (i.e., 100 percent of energy – ( $DV_{\text{fat}} + DV_{\text{carbohydrate}}$ )). The 2007 ANPRM requested comment on whether the DV for protein should be based on (1) the approach recommended in the IOM Labeling Report; (2) the midpoint of the AMDR for protein (i.e., 22.5 percent); or (3) the EAR or RDA for protein. We received comments on each of these approaches (Ref. 47). Overall, comments supported the approach recommended in the IOM Labeling Report and maintaining the DV of 50 g/d.

We considered current scientific recommendations and agree with the comments that supported the continued use of the current approach. First, as explained in sections II.B. and II.D., we are not proposing to change the DRVs for fat (30 percent of calories from fat or 65 g) or carbohydrate (60 percent of calories from carbohydrate or 300 g). Applying the IOM Labeling Committee's recommended approach, given our tentative conclusions on DRVs for fat and carbohydrates, that approach would result in no change to the DRV for protein, i.e., 10 percent ( $100 - (60 + 30)$ ) of calories from protein.

Second, at 10 percent of caloric intake and using a reference energy intake of 2,000 calories, the DRV for protein is set at 50 g, which is relatively close to the IOM's RDAs for men and women. The RDAs, which represent values that meet the needs of almost all (97 to 98 percent) individuals in a group, are set at 0.80 g/kg for men and women who are 19 years and older, 0.85 g/kg for boys and girls 14 to 18 years of age, and 0.95 g/kg for boys and girls 4 to 13 years of age. Using reference weights established for age and gender groups, the resulting values

are 56 g/d for males and 46 g/d for females who are 19 years of age or older (not including pregnant and lactating women), 52 g/d for males and 46 g/d for females between the ages of 14 through 18 years of age, 34 g/d for males and females between the ages of 9 and 13 years, and 19 g/d for males and females between the ages of 4 through 8 years. Thus, the DRV of 50 g for protein falls within the range of the RDAs calculated using reference weights.

We do not consider the midpoint of the AMDR of 22.5 percent of energy intake to provide the most appropriate basis for a DRV for protein. We have no data to show that protein intakes are inadequate or that setting a higher DRV that is based on the midpoint of the AMDR is needed to prevent chronic diseases such as cardiovascular disease, obesity, and sarcopenia, as asserted by some comments (Ref. 47). The AMDR is a range of intakes for a particular energy source that is associated with reduced risk of chronic diseases while providing adequate intakes of essential nutrients (Ref. 20). The DRV of 10 percent of calories from protein falls within the AMDR. Thus, the DRV for protein falls within a range of protein consumption that is associated with a reduced risk of chronic disease while providing essential nutrients.

Finally, we consider the use of the population-weighted EAR to be inappropriate. First, as the comments pointed out (Ref. 47), using the population-weighted EAR could lead to inadequate consumption in some subpopulations, such as males 19 years and older. In addition, the EARs for protein are expressed in terms of g/kg of body weight and based on consumption of good quality or "complete" protein. In order to calculate a DRV from the population-weighted EAR for the purposes of nutrition labeling, a reference body weight would have to be selected. Although we could use the EER predictive equations included in the IOM's DRI macronutrient report (Ref. 50) to determine a reference body weight, these values may be inappropriate for the general U. S. population, which has a high percentage of overweight individuals. The IOM

Labeling Report stated that deriving a label reference value for protein based on values from the EER predictive equations may not be appropriate for large segments of the North American population for the same reason (Ref. 25 ).

Therefore, we tentatively conclude that the DRV for protein should continue to be based on 10 percent of calories. Accordingly, we are not proposing to change the DRV of 50 g for protein.

## F. Sodium

### 1. Mandatory Declaration

FDA regulations require the declaration of sodium content on the Nutrition Facts label (§ 101.9(c)(4)). The 2007 ANPRM did not ask any questions about the mandatory declaration of sodium, but one comment that recommended the declaration of sodium should remain mandatory because the information can help consumers who are concerned about sodium and salt make appropriate food choices.

Americans 4 years and older consume an average of approximately 3,650 mg sodium/d (NHANES 2003-2006), which is more than twice the amount required to meet their adequate intake (1,500 mg/day for individuals 9 to 50 years old). Evidence continues to support the association between increased sodium consumption and increased blood pressure. In 2005, the IOM noted the direct relationship between sodium intake and increased blood pressure (Ref. 10). The 2010 DGAC and the 2013 IOM committee on Sodium Intake in Populations (Ref. 87) concluded that a strong body of evidence has been documented in adults that as sodium intake decreases, so does blood pressure (Ref. 30). We agree with the comment that information about sodium content on the food label can help consumers make appropriate food choices.

Therefore, we tentatively conclude that declaration of sodium should remain mandatory so consumers are provided information necessary to assist them in maintaining healthy dietary practices. Accordingly, we are not proposing to amend the current requirement for declaration of sodium in § 101.9(c)(4).

## 2. DRV

a. Need to update the DRV--The DRV for sodium is 2,400 mg (§ 101.9(c)(9)). New scientific data and consensus reports on sodium published since the 1993 final rule (58 FR 2206 at 2224) highlight the need to reconsider the DRV. Recent key consensus reports and recommendations that FDA reviewed in reconsidering the DRV are as follows:

i. IOM DRI Electrolytes Report. In 2005, the IOM established AIs and ULs for sodium (Ref. 10). The IOM found that data from dose-response trials for determining the daily requirement for sodium were insufficient to establish an EAR for sodium and, thus, an RDA could not be determined and an AI was set. The AIs for sodium are intake levels that meet or exceed the daily nutrient requirement, i.e., the recommended daily average intake levels that are needed to meet the sodium needs of most healthy and moderately active individuals, are 1,500 mg/d for individuals 9 to 50 years, 1,300 mg/d for individuals 51 to 70 years, and 1,200 mg/d for individuals older than 70 years and for children 4 to 8 years of age. AIs meet or exceed the intake levels required to meet nutrient needs and there is no benefit in consuming a nutrient in excess of its AI.

Data available to the IOM showed that; (1) a carefully planned diet that provided an average of approximately 1,500 mg/d of sodium can meet recommended intakes of other nutrients; (2) 1,500 mg/d exceeds the levels of sodium intake that have been associated with effects of inadequacy, such as adverse effects on blood lipid concentrations and insulin

resistance; and (3) 1,500 mg/d allows for sodium sweat losses in acclimatized individuals who are exposed to high temperatures or who become physically active. The AI does not apply to individuals who are highly active and workers who are exposed to heat stress that lose large volumes of sodium in sweat (Ref. 10).

ULs are the highest level of daily nutrient intake that is likely to pose no risk of adverse health effects to almost all individuals in the general population (Ref. 10). The major adverse and dose-dependent effect of increased sodium intake is elevated blood pressure and the IOM noted that the relationship between sodium intake and blood pressure is continuous, making it difficult to set a precise UL because other environmental factors (weight, exercise, potassium intake, dietary pattern, and alcohol intake) and genetic factors also affect blood pressure. The ULs for sodium are 2,300 mg/d for all individuals ages 14 years and older, 1,900 mg/d for children 4 to 8 years old, and 2,200 mg/d for adolescents 9 to 13 years old. The UL is not intended to be a recommended intake level to encourage, but rather a level not to exceed.

The IOM stated that the UL may be lower than 2,300 mg/d among certain groups who are at increased risk of the blood pressure-raising effects of increased sodium intake (e.g., older individuals, African Americans, and individuals with hypertension, chronic kidney disease, or diabetes), but insufficient data prevented IOM from defining a specific UL for these groups. Instead, the IOM set the same UL for these population groups as the one for the general population (i.e., 2,300 mg/d), with the acknowledgment that the actual UL for this group may be lower.

ii. IOM Report on the Strategies to Reduce Sodium Intake in the United States (IOM Sodium Strategies Report). After considering current trends in hypertension, sodium consumption, sodium content of the food supply, and existing strategies for sodium reduction,

the IOM developed various strategies for reducing dietary sodium intake to levels recommended by the 2005 DGA. Among various recommendations to Government Agencies, food manufacturers, consumers, and other stakeholders, the IOM recommended that FDA adopt 1,500 mg as the DV for sodium, given that sodium is an essential nutrient and that, unlike in 1993 (58 FR 2206 at 2224), a reference value of adequacy is now available (i.e., the AI of 1,500 mg/d).

iii. 2010 DGA. The 2005 DGA made a key recommendation for the general U. S. population to consume less than 2,300 mg/d of sodium and that individuals with hypertension, African-Americans, and middle-aged and older adults should aim to consume no more than 1,500 mg/d of sodium (Ref. 36). In 2010, the DGAC evaluated evidence considered in the 2005 DGAC report in addition to new research on the relationship between sodium intake and blood pressure, focusing on the strength of the scientific evidence (Ref. 30). The 2010 DGAC report noted that 1,500 mg/d should be the intake goal for the general U. S. population. Further, the DGAC noted that, given the current U. S. marketplace and the resulting excessively high sodium intake, it will be challenging to achieve the lower level. The 2010 DGA, considering the 2010 DGAC conclusions, recommended a reduction in sodium intake to less than 2,300 mg/d and a further reduction to 1,500 mg/d among African Americans, individuals with hypertension, diabetes, or chronic kidney disease, and individuals ages 51 years or older.

iv. IOM Report on Sodium Intake in Populations, Assessment of Evidence, 2013 (Ref. 87). The charge to the committee focused on literature published since 2003, therefore they reviewed literature between 2003 and 2012. The committee assessed the benefits and adverse outcomes (if any) of reducing sodium intake, particularly in the range of 1,500 to 2,300 mg/d, with an emphasis on the subgroups known to be at increased risk of the blood pressure-raising effects of increased sodium intake. Based on the review of studies that assessed cardiovascular

events and mortality, the committee found that evidence from studies on direct health outcomes is inconsistent and insufficient to conclude that lowering sodium intakes below 2,300 mg/d will increase or decrease the risk of CVD outcomes or all-cause mortality in the general U. S. population. The committee also concluded that the evidence from direct health outcomes does not support recommendations for subgroups (people with diabetes, chronic kidney disease and pre-CVD) to lower their sodium intake to or even below 1,500 mg/d . No relevant evidence was found on health outcomes for the other population subgroups considered (i.e., African Americans and persons 51 years of age and older).

b. CSPI petition--In 2005, we received a citizen petition from CSPI (2005 CSPI petition) requesting, among other sodium related issues, that FDA initiate rulemaking to reduce the DRV for sodium from 2,400 to 1,500 mg (Docket No. FDA-2005-P-0196 (formerly Docket No. 2005P-0450)) (<http://www.regulations.gov/#!docketDetail;D=FDA-2005-P-0196>). Citing the 2005 DGA, the petition requested that FDA adopt a DV of 1,500 mg because that is the recommended maximum intake for roughly one-half of the adult population (i.e., people with hypertension, African-Americans, and middle-aged and older people). According to the petition, when recommended intake levels vary among population groups, FDA has typically been conservative, choosing a DV that is most protective. In this proposed rule, we are responding to the petition's request to reduce the DRV for sodium from 2,400 mg to 1,500 mg. The petition's other requests are outside the scope of this rulemaking.

c. Comments to 2007 ANPRM--In the 2007 ANPRM, we asked whether a new DV for sodium should be based on the UL or on the AI. We also asked whether the UL, were it to be used, should reflect the same approach (population-weighted or population-coverage) as the other DRIs. While a few comments supported retaining the current DRV of 2,400 mg, the

majority of comments supported using the UL of 2,300 mg/d. Some other comments recommended setting a DV for sodium based on the AI of 1,500 mg/d. One comment urged that we adopt a tiered two-phase, step-down approach establishing an interim DRV of 2,000 mg in 2013 and a final revised DRV of 1,500 mg by 2020. See also (Ref. 47).

d. Options Considered--When the Nutrition Facts label was developed in the early 1990s, no RDA or Estimated Safe and Adequate Daily Dietary Intake (ESADDI) levels were available for consideration. While the National Academy of Sciences established 500 mg/d as an estimated minimum requirement for healthy adults in 1989, the Agency relied on the recommendation from 1989 National Research Council Report Diet and Health: Implications for Reducing Chronic Disease Risk (Ref. 88) that provided a quantitative intake recommendation for salt, based on blood pressure, that was equivalent to 2,400 mg/d as a value that consumers should not exceed (58 FR 2206 at 2223, 2224). There is debate in the scientific community about the appropriate DV for sodium, taking into account its essentiality in relatively small amounts as well as its association with increased blood pressure at greater but varying levels of intake.

Current recommendations recognize the benefits of reduced sodium intake in the general population, despite the heterogeneity among individuals in blood pressure responses to changes in sodium intake. Although several factors influence inter-individual variability in blood pressure responses to changes in dietary sodium, certain population groups have been reported to have a higher prevalence of salt sensitivity and are considered to be most at risk of sodium-related chronic disease. Salt sensitivity is the extent of change in blood pressure in response to a change in salt intake (Ref. 10). Salt sensitivity differs among subgroups of the population as well as among individuals within a subgroup. Subgroups that have been reported to have a high prevalence of salt sensitivity include individuals 51 years of age and older, African Americans,

and individuals with hypertension, diabetes or chronic kidney disease. The 2010 DGA recommended that Americans reduce sodium intakes and also noted that these population subgroups, representing nearly half of the U. S. population, would benefit from even greater reductions in sodium intake than the general population. We have considered the challenges related to lowering the DV for sodium. For example, lowering the value on which the percent DV declaration is based would likely require efforts to ensure consumer understanding of the new percent DV declaration of sodium on the Nutrition Facts label. Based on recent dietary recommendations from consensus reports, currently available scientific evidence, comments in response to the 2007 ANPRM, and the 2005 CSPI petition, we considered the following options for updating the DV for sodium:

- (1) A DRV of 2,300 mg which reflects the UL for individuals aged 14 years and older;
- (2) an RDI of 1,500 mg which reflects the AI for individuals 9 to 50 years of age; and
- (3) alternative approaches such as retaining a DRV of 2,400 mg, using a tiered approach or setting a DRV of 1,900 mg based on the UL for children 4 to 9 years of age.

- i. DRV of 2,300 mg/d. A DRV of 2,300 mg, which represents the UL for the majority of the population (persons 14 years of age and older), would be consistent with both the 2005 and 2010 DGA recommendations for sodium intake for the general population, as well as the 2013 IOM report on Sodium Intake in Populations. However, while a DRV of 2,300 mg would reflect the UL that is applicable to 88 percent of the U. S. population, including those who are susceptible to the blood pressure-raising effects of sodium, it would exceed the UL for children 4 to 13 years of age which is 1,900mg/day for children 4-8 years of age and 2,000mg/day for children 9-13 years of age..

Setting the DV at 2,300 mg would classify the level as a DRV (rather than an RDI) and represent a reference intake level not to exceed. As such, it would be consistent with our current and proposed approach to using DRVs for other nutrients that should be limited in the diet and for which there are concerns of excess intake and risk of chronic disease or health-related conditions, for example, saturated fat and cholesterol. The current and proposed DRVs for saturated fat and cholesterol are based on quantitative intake recommendations and underlying science that links the excess intake of these nutrients to specific adverse health effects (Ref. 6) (see sections II.B.2 and II.C.). We do note, however, that unlike saturated fat and cholesterol, sodium is an essential nutrient and, in the DRI Electrolytes report, the IOM established an AI for sodium.

Results from the FDA Health and Diet Surveys have shown that consumers are aware that too much sodium is unhealthy (Refs. 39 to 41) and this awareness would suggest consumer acceptance of a DV based on a level not to exceed would be consistent with a DRV of 2,300 mg. Changing the DRV from 2,400 mg to 2,300 mg would likely result in less consumer confusion than changing the DRV to an RDI (a level to achieve) of 1,500 mg. Moreover, we have no data to suggest that lowering the reference value for the percent DV could result in consumer confusion, as claimed by a commenter (Ref. 47).

ii. RDI of 1,500 mg. An RDI of 1,500 mg, based on the highest AI (i.e., among adults aged 19 to 50 years), would provide a daily average intake level that would reflect a low prevalence of inadequate sodium intakes of healthy and moderately active individuals while allowing for adequate intakes of other essential nutrients. As opposed to 2,300 mg, a DV of 1,500 mg would classify the level as an RDI representing a reference intake level to achieve. The 2005 IOM electrolytes report reviewed the evidence on low sodium intake and blood lipid

concentrations and insulin resistance and noted that the AI of 1,500 mg/d exceeds the levels of sodium intake (typically less than 700 mg/d) that have been associated in some studies with adverse effects of blood lipid concentrations and insulin resistance (Ref. 10). The 2005 IOM electrolytes report reviewed the evidence for plasma renin and concluded that, in contrast to blood pressure, there is no consensus on the interpretation of plasma renin activity and its role in guiding therapy for high blood pressure (Ref. 10). Similar to plasma renin activity, the evidence for the role of sympathetic nerve activity and aldosterone is limited, and therefore neither is recognized as surrogate endpoints for CVD risk. Therefore, the AI of 1,500 mg/d exceeds the levels associated with low sodium intake and the previously discussed adverse effects.

Using the population-coverage AI to set the RDI for sodium would be consistent with the proposed RDIs for other essential vitamins and minerals for which AIs are established (e.g., vitamin K and choline) (see section II.I.). AIs are similar to RDAs in that they meet the needs of essentially all members of the population. Thus, using an AI as a quantitative intake recommendation for setting an RDI would be consistent with the proposed RDIs for other essential minerals that have AIs or RDAs, such as potassium and calcium. Traditionally, we have based the RDI for essential nutrients on quantitative intake recommendations that reflect the intake level necessary to meet the daily physiological needs for that nutrient. However, unlike the consumption of other vitamins and minerals, the majority of the population consumes sodium at levels that exceed the AI and the UL. This makes sodium unique in comparison to other vitamins and minerals for which people generally must strive to meet their daily needs.

In addition, an RDI of 1,500 mg would be consistent with the 2010 IOM Sodium Strategies Report (Ref. 89). The IOM recommended that FDA base the DV for sodium on the AI of 1,500 mg/d. First, the IOM stated that using the AI is consistent with the approach used

for all other essential nutrients, where the DV is based on a reference value of adequacy rather than a reference value of safety. Second, although consumer data were not provided, the IOM strategies report argued that the use of the AI could better inform consumers of the actual contribution of sodium content to total sodium needs as an essential nutrient. Third, the IOM stated that adopting the AI would avoid misleading consumers into thinking that the sodium content of foods is more favorable than is actually the case. As such, from a public health perspective, the AI would provide a truer picture for the consumer of the contribution of the particular foods in assembling a healthful diet and is preferable for this purpose over the UL. Finally, the IOM opined that lowering the DV might act as an incentive for companies to reduce the sodium content of their foods because reducing the DV would result in a higher value of percent DV declared on the label if sodium content remained unchanged.

The 2013 IOM Sodium Intake in Populations Committee concluded that the evidence was insufficient and inconsistent to recommend sodium intake levels below 2,300 mg/d for the general U. S. population based on the direct outcomes of CVD or all-cause mortality. While this recommendation does not address blood pressure or essentiality, it provides a level that the general population should seek to reduce their consumption to and therefore is a consideration in our proposal.

ANPRM comments pointed out challenges related to the feasibility of achieving a DV of 1,500 mg given the current marketplace and patterns of sodium consumption as well as changes in our nutrient content claims. If we were to adopt a DV of 1,500 mg, we anticipate that consumer education efforts would be needed to help consumers understand that the updated DV for sodium is a level to achieve rather than a level to consume less than and also that consuming in excess of this level would not be helpful. Additionally, the IOM set the AI, in part, at a level

that would allow individuals to meet the recommended intakes of other nutrients if they adopted a carefully planned diet (Ref. 10) and consumer education efforts would need to communicate that 1,500 mg/d is a level that consumers should achieve rather than not exceed. While the Agency is considering ways to support the reduction of sodium in the food supply (76 FR 57050), significant changes in the food supply would be needed to achieve this goal.

An updated DV for sodium based on 1,500 mg/d would perhaps necessitate revising other relevant regulatory requirements such as nutrient content claims, however such revisions would be less likely if the DV was updated to 2,300 mg. Previously, our decision to retain the sodium level for a "healthy" claim (§ 101.65) at 480 mg/reference amount customarily consumed (RACC) was based, in part, on technological barriers and product acceptance issues by consumers with the more restrictive level of 360 mg/RACC (70 FR 56828; September 29, 2005). We acknowledge concerns from comments that consumers may find it difficult to reduce dietary sodium levels to 1,500 mg/d.

iii. Alternative approaches.

A few comments suggested retaining 2,400 mg as the DRV for sodium. Retaining the DRV of 2,400 mg would exceed the UL for sodium for the entire population and there is no scientific evidence to support this level. Therefore, we do not consider 2,400 mg an appropriate DRV for sodium going forward. Also, based on ANPRM comments, we considered setting an interim DRV of 2,300 mg that would be further lowered to an RDI of 1,500 mg over time, providing companies a longer time to manufacture new foods or reformulate existing products to lower the sodium content. This approach would address concerns regarding the feasibility of individuals being able to meet an RDI of 1,500 mg given taste preferences and sodium content of foods in the current marketplace. A tiered approach would help to gradually achieve the

adequate intake level of 1,500 mg/d and would give manufacturers time to develop lower sodium products and for consumers to adjust their taste preferences. In addition, this approach would be consistent with the 2010 DGAC recommendations which suggested that reduction in sodium intakes to 1,500 mg/d among Americans should occur gradually over time to allow for adjustments in taste perceptions and to accompany changes in the sodium content of foods in the marketplace.

We tentatively conclude that there is inadequate justification in consensus reports or arguments presented by comments (Ref. 47) to propose a tiered option. While levels of sodium intake may need to decrease gradually due to time needed for modifications to the sodium content of the food supply and consumer taste preferences, the DV for sodium should reflect an amount that will assist consumers in maintaining healthy dietary practices and in understanding the relative significance of the percent DV for a particular food in the context of the total daily diet. Moreover, DVs are based on scientific data supporting healthy dietary practices, not on the levels of a nutrient present in the food supply.

We also considered using 1,900 mg/d, the UL for children 4 to 8 years of age, to set the DRV for sodium. Using the lowest UL for a population above 4 years of age is consistent with the population-coverage approach discussed in section II.1.5. In this case, it is a population-coverage approach that is protective for the age and gender subpopulation with the lowest relative UL, providing an intake level that is likely to pose no risk for any age or gender subpopulations. This is in contrast to the population-coverage approach, using the RDA or AI for other essential vitamins and minerals, to ensure that all age and gender subpopulations consume adequate amounts. However, a DRV of 1,900 mg is not aligned with any

recommendations from consensus reports including the 2010 IOM Sodium Intake in Populations and was not suggested by any comments.

e. Proposed DV--After considering the options discussed previously, we are proposing to set a DRV of 2,300 mg for sodium based on the UL for individuals ages 4 years of age and older (proposed § 101.9(c)(8)(iv)). First, a DRV of 2,300 mg would be consistent with the current sodium intake recommendations from consensus reports. Second, a DRV of 2,300 mg would be consistent with our current and proposed approach for other nutrients that should be limited in the diet and for which there are concerns of excess intake and risk of chronic disease and health-related conditions. Third, consumers are generally aware that too much sodium is not healthy and therefore the current consumer education messaging is consistent with a DRV of 2,300 mg.

For the reasons explained previously, we tentatively conclude that a DRV of 2,300 mg for sodium is the most appropriate DV to assist consumers in maintaining healthy dietary practices and in understanding the relative significance of the sodium content within the context of a total daily diet. We invite comment on our consideration of various options and tentative conclusions presented in this section. In particular, we invite comment on: (1) The rationale for the proposed DRV of 2,300 mg of sodium; (2) whether an RDI of 1,500 mg would be more appropriate and why; and (3) whether any alternative approaches for selecting a DV for sodium and their public health bases for these approaches could be more appropriate and why. We are also interested in data and factual information on consumer understanding, interpretation, and use of the percent DV of sodium declared on food labels, including the understanding and potential influences of a DV that reflects an RDI based on an AI (an intake level to not consume less of), instead of a DRV based on a UL (an intake level not to exceed).

#### G. Fluoride

## 1. Voluntary Declaration

FDA regulations do not require or permit the declaration of fluoride on the Nutrition Facts label. In 1993, no U. S. consensus report had set a quantitative intake recommendation for fluoride. The 2007 ANPRM did not ask questions regarding the declaration of fluoride, but several comments supported the voluntary declaration of fluoride in mg or mcg amounts (Ref. 47). We are considering in this proposed rule whether fluoride should be required or permitted to be declared or whether the lack of provisions should be maintained.

Fluoride is a nonessential nutrient, but there is well established evidence for the role of fluoride in reducing the risk of dental caries (Ref. 90). The IOM set a quantitative intake recommendation for fluoride based on its role in the reduction of risk of dental caries. Additionally, in 2006, a FDAMA notification for a health claim for fluoride in bottled water and dental caries was submitted to us under section 403(r)(2)(G) of the FD&C Act (Ref. 91). We did not object to the notification, indicating that we considered the evidence submitted to be sufficient for bottled water that meets the standards of identity and quality set forth in § 165.110 and the general requirements for health claims in § 101.14 to bear the claim (Ref. 91). Given that the positive health effects of fluoride are well-established, we tentatively conclude that declaration of fluoride content of a food can provide consumers with information to assist them in maintaining healthy dietary practices. However, as discussed in section II.G.2., a DRV cannot be established based on available quantitative intake recommendations. Thus, while fluoride is a nutrient with public health significance, an appropriate quantitative intake recommendation is not available for setting a DRV.

Therefore, consistent with the factors we consider for declaration of non-statutory nutrients discussed in section I.C., we are proposing to amend § 101.9(c)(5) to provide for

voluntary declaration of fluoride. In addition, consistent with existing provisions for voluntary declaration of other nutrients, we are proposing that the declaration of fluoride would be mandatory when a claim about fluoride is made on the label or in labeling of foods. We are also proposing that when fluoride content is declared, it must be expressed as zero when a serving contains less than 0.1 mg of fluoride, to the nearest 0.1 mg increment when a serving contains less than or equal to 0.8 mg of fluoride, and the nearest 0.2 mg when a serving contains more than 0.8 mg of fluoride, consistent with how we have approached incremental values for other nutrients that are present in food in small amounts.

## 2. DRV

FDA regulations do not provide an RDI or DRV for fluoride. The 2007 ANRPM discussed the DRIs for fluoride and asked whether we should establish a DV, given the availability of an AI. We considered current recommendations and scientific evidence as well as comments received (Ref. 47).

In 1997, the IOM established DRIs (AIs and ULs) for fluoride (Ref. 90). The AI was set at 3 mg/d for women 19 years and older and 4 mg/d for men 19 years or older, to represent the intake value that reduces the occurrence of dental caries maximally in a group of individuals without causing unwanted side effects. AIs for children are 0.7 mg/d (1 through 3 years), 1 mg/d (4 through 8 years), and 2 mg/d (9 through 13 years). In addition, the IOM set a UL for fluoride at 10 mg/d (0.1 mg/kg/d) for individuals older than 8 years, based on data that suggest that increased risk of developing early signs of skeletal fluorosis is associated with fluoride intakes greater than 10 mg/d. The UL for children 4 through 8 years is 2.2 mg/d based on risk of developing moderate enamel fluorosis.

A recent report highlighted the potential adverse impact of excess fluoride intake (Ref. 92). These adverse impacts include moderate enamel fluorosis in children up to 8 years and skeletal fluorosis for individuals older than 8 years. In 2010, the Environmental Protection Agency (EPA) published a report on exposure of fluoride from various sources. This report provided a benchmark of no more than 0.08 mg/kg/d of total fluoride intake to protect 99.5 percent of the population from severe dental fluorosis (Ref. 92). These benchmark levels (e.g., 1.68 mg/d for 4 to 7 years; 2.56 mg/d for 7 to 11 years; 4.08 mg/d for 11 to 14 years of age; and 5.6 mg/d for adults) are considerably lower than the ULs set by IOM in 1997.

Thus, although the IOM set AIs for fluoride based on its role in reducing the risk of dental caries, more recent conclusions have highlighted concern about dental fluorosis associated with excess intakes. Because an RDI of 4 mg, using the population-coverage AI of 4 mg/d, exceeds or is equivalent to EPA's benchmark values for children 4 to 14 years of age (1.68 to 4.08 mg/d), we are not proposing to set a DRV for fluoride.

We considered concerns expressed by comments that a DRV should not be established because fluoride is not an essential nutrient. That fluoride is not essential is not, in itself, a justification for not establishing a DV for fluoride, because there is evidence demonstrating that dietary fluoride exposure is beneficial to public health owing to its ability to inhibit the development of dental caries in both children and adults (Ref. 90). However, we are not proposing to set a DRV for fluoride for other reasons as explained previously. We also do not consider that the DRV for fluoride should be set at zero because of concerns with adverse health effects and toxicity, as suggested by a comment. The IOM established an AI for fluoride based on risk reduction of dental caries. In addition, the ULs for children and adults that are set based on dental and skeletal fluorosis are greater than zero. Moreover, FDA regulations other than

those related to nutrition labeling are intended to prevent excessive addition of fluoride in foods (§§ 165.110 and 170.45).

#### H. Essential Vitamins and Minerals of Public Health Significance

In addition to sodium, a statutorily required nutrient, FDA regulations require the declaration of four essential vitamins and minerals, namely, vitamin A, vitamin C, calcium, and iron (§ 101.9(c)(8)(ii)). Vitamins and minerals that may be declared voluntarily are vitamin D, vitamin E, vitamin K, vitamin B<sub>6</sub>, vitamin B<sub>12</sub>, thiamin, riboflavin, niacin, folate, biotin, pantothenic acid, phosphorus, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, and potassium. In 1993, we identified vitamins A and C, calcium, and iron for mandatory declaration because we considered them to be nutrients of public health significance based on their inadequate dietary intakes among specific segments of the U. S. population and because they were identified as nutrients of potential public health significance in consensus reports (Refs. 88,93 to 95) (58 FR 2079 at 2106). We continue to consider, consistent with the rationale put forth in 1993, that a vitamin or mineral's public health significance should be the key factor in mandatory labeling (58 FR 2079 at 2106).

In this section of the proposed rule, we discuss essential vitamins and minerals that are not expressly required to be declared by statute (referred to as "non-statutory"). We are using our discretion, as described in this document, to propose mandatory declaration of certain non-statutory essential vitamins and minerals and voluntary declaration of others. Our tentative conclusions are based on an assessment of scientific data available for these nutrients, and consideration of the factors discussed in section I.C. (explained in this document). The RDIs that we are proposing for the declaration of vitamins and minerals are discussed in section II.I.

We conducted an analysis of available data to determine the public health significance of non-statutory essential vitamins and minerals. The 2010 DGA identified nutrients of public health concern for the general U. S. population using criteria that are similar to factors that FDA considered in its own analysis (Ref. 6). The factors and the evaluation process used in our analysis, discussed in greater detail in Ref. 48 , incorporate whether a DRI (i.e., RDA or AI) is based on a chronic disease risk (e.g., osteoporosis), a health-related condition (e.g., high blood pressure), or a nutrient deficiency with clinical significance (e.g., low iron storage leading to iron deficiency anemia) and whether national survey data on nutrient intake, and/or, when available, biomarkers of nutrient status, provide evidence of inadequate intakes in the general healthy U. S. population (4 years of age and older). Furthermore, we consider whether a substantial prevalence exists in the general population of a chronic disease, health-related condition, or nutrient deficiency with clinical significance that was linked to the particular nutrient (e.g., potassium and risk of high blood pressure).

To estimate the prevalence of nutrient adequacy or inadequacy in the U. S. population, we compared dietary intake data with the EAR or AI (whichever is established by the IOM for a particular nutrient) (Ref. 96) and, when reliable biomarkers of nutritional status were available, we compared the biomarker survey data with the data on adequacy of nutrient intake. The use of reliable status biomarker data provides assessments of nutrient status, independent of subjective factors associated with assessing nutrient intake, such as underreporting of food intake (Ref. 97 pp. 373, 513, 534, 602, and 606). In the 2007 ANPRM, we sought input on whether vitamin A, vitamin C, calcium, and iron are still considered to be of public health significance; and 2) whether there are other micronutrients of public health significance. We received several comments in response to these questions (Ref. 47).

Based on our analysis of data, and considering the factors for mandatory and voluntary declaration discussed in section I.C. and the comments received, as discussed in this document, we are proposing to: (1) With respect to essential vitamins and minerals that are currently required to be declared, retain mandatory declaration of calcium and iron and provide for voluntary declaration of vitamins A and C; and (2) with respect to essential vitamins and minerals that are permitted to be declared, require the declaration of potassium and vitamin D and retain voluntary declaration of others. We discuss these proposed changes in this document.

#### 1. Essential Vitamins and Minerals That Are Mandatory

a. Calcium--Calcium content must be declared as a percent DV on the Nutrition Facts label (§ 101.9(c)(8)(ii)). In 1993, we required the declaration of calcium in nutrition labeling because: (1) There were a limited number of calcium-rich foods in the food supply; (2) calcium intakes in the United States were generally marginal; (3) adequate calcium intakes are needed to allow for optimal bone mass development during childhood and young adulthood (55 FR 29487 at 29501); and (4) calcium was identified as a nutrient of public health significance in the 1990 IOM report (Ref. 95) and in other consensus reports (Refs. 88,93,94) (58 FR 2079 at 2106). In response to the 2007 ANPRM, many comments maintained that calcium is still considered a nutrient of public health significance, especially in bone development, and therefore should be retained as a mandatory nutrient on the Nutrition Facts label.

Our analysis of NHANES (2003-2006) data shows that usual calcium intakes among the U. S. population continue to be low. About 49 percent of individuals ages 4 years and older have usual calcium intakes from conventional foods below the EAR, and 37 percent have intakes from both conventional foods plus supplements below the EAR (table 1). The 2010 DGA, too, recognized that low intakes of calcium are a public health concern for the general U. S.

population (Ref. 6). We are unable to consider biomarker data because sensitive biochemical indicators reflecting calcium nutritional status are lacking.

In setting DRIs for calcium, the IOM reviewed various endpoints (e.g., bone health, cancer, cardiovascular disease and diabetes), and bone health was the only endpoint with sufficient evidence to set a DRI (Ref. 22 ). Therefore, the IOM set age- and gender-specific DRIs based on the level of calcium intake consistent with bone accretion, achieving and maintaining bone calcium balance, minimizing the degree of bone loss, and reducing the risk of fracture in later stages of life (Ref. 22). The DRIs for calcium assume adequate intakes of vitamin D, a nutrient which is essential for promoting calcium absorption in the gut and for maintaining adequate calcium levels in the blood (Ref. 22). Building strong bones during childhood and adolescence can help prevent osteoporosis (the most common bone disease) later in life. Adequate calcium intakes are needed to allow for optimal bone mass development during childhood and young adulthood and to decrease rate of bone loss in adults (Ref. 22). An estimated 10 million Americans over 50 years of age have osteoporosis, while another 34 million are at risk and an estimated 1.5 million people suffer an osteoporotic-related fracture each year (Ref. 98). Furthermore, based on 2005-2006 NHANES data, about 5.3 million older men and women in the United States have osteoporosis at the femur neck, and 34.5 million more have osteopenia (low bone mass) in the femur neck (Ref. 99).

In addition, we independently reviewed data related to calcium intake and risk reduction of osteoporosis (§ 101.72) and authorized two health claims for this association, signifying calcium's critical role in the reduction of risk of this chronic disease in the general healthy population.

In view of the benefits of adequate calcium intake on bone health, reflected in the IOM's DRIs, relatively low intakes of calcium, and the high prevalence of osteoporosis and osteopenia among the U. S. population, we tentatively conclude that calcium is a nutrient of public health significance and its declaration continues to be necessary to assist consumers in maintaining healthy dietary practices. Therefore, consistent with the factors we consider for mandatory declaration of non-statutory nutrients (see section I.C.), we are not proposing any changes to the current requirement for declaration of calcium on the Nutrition Facts label, as specified in § 101.9(c)(8)(ii).

b. Iron--Iron must be declared as a percent DV on the Nutrition Facts label (§ 101.9(c)(8)(ii)). In 1993, we required the declaration of iron because (1) iron was identified as a nutrient of public health significance in a 1990 IOM report (Ref. 95) and in other consensus reports (Refs. 88,93,94); and (2) iron deficiency was a risk for certain segments of the U. S. population (i.e., young children, adolescents and women of childbearing age and pregnant women, especially those with low incomes) (58 FR 2079 at 2106). In response to the 2007 ANPRM, comments suggested retaining the mandatory declaration of iron because it is a nutrient of concern for women of childbearing age identified by the 2005 DGA (Ref. 36) and substantial numbers of adolescent females and women of childbearing age are iron deficient.

Our analysis of NHANES (2003-2006) intake data shows that about 3.5 percent of the population ages 4 years and older (excluding pregnant and lactating women) have inadequate iron intakes from conventional foods (i.e., an intake below the EAR), and about 3.3 percent have inadequate iron intakes from conventional foods and dietary supplements (table 1). Subpopulation analyses of these NHANES 2003-2006 data shows that about 11.2 percent of women of childbearing age (12 to 49 years of age) continue to have intakes below the EAR, from

conventional foods only and 10.4 percent continue to have intakes below the EAR from conventional foods plus dietary supplements (table 1).

We also considered data for several status biomarkers related to iron nutrition, in addition to intake data. Serum ferritin is the major iron-storage compound and its concentration declines in the early stages of the development of iron deficiency (Refs. 100 and 101). Although low serum ferritin concentration is an indicator of early iron deficiency, it does not necessarily reflect the severity of iron depletion as it progresses (Ref. 101). In addition to determining serum ferritin, when relevant NHANES data were available, we also considered iron deficiency based on estimating stored body iron using the ferritin model and the body iron model (Ref. 102). Compared to the ferritin model, the body iron model is reported to produce lower estimates of prevalence of iron deficiency, better predict anemia, and be less affected by inflammation, although this model has some limitations (Ref. 103). Data from NHANES 1999-2002 for the general U. S. population showed a prevalence of iron deficiency, based on serum ferritin concentration (less than 15 nanograms (ng)/mL), body iron stores (based on the ferritin model), and iron deficiency anemia (defined as having iron deficiency and a low hemoglobin value) of 8.3, 6.5 and 1.9 percent, respectively (table 1). The IOM set age and gender specific DRIs (EARs and RDAs) based on factorial modeling, which included basal iron losses, menstrual losses, fetal requirements in pregnancy, increased requirements during growth for the expansion of blood volume, and/or increased tissue and storage iron (Ref. 100). Although the DRIs were not based directly on a chronic disease risk, iron deficiency and low iron stores over time will lead to iron deficiency anemia, an advanced stage of iron deficiency (Ref. 100). Anemia is associated with poor cognitive function, lower work performance, and low endurance in the

general population; delayed psychomotor development in infants; and adverse pregnancy outcome (Ref. 100).

Relevant biomarker data were available from NHANES 2003-2006 for certain subpopulations such as women of childbearing age (12 to 49 years old). Analyses of these data showed that about 14 percent of women of childbearing age (12 to 49 years) had serum ferritin concentration less than 15 ng/mL, while 10 and 14.5 percent of women had inadequate stores of body iron based on the body iron model or ferritin model, respectively (table 1). In addition, about 4.7 percent of these women had iron deficiency anemia. Based on these prevalence rates, the absolute numbers of individuals with iron deficiency in women of childbearing age using 2010 projected U. S. Census data translate into 7.2 or 11.6 million women of childbearing age (12 to 49 years of age) with inadequate iron stores based on body iron model or ferritin model, respectively. About 3.76 million of these women are considered to have iron deficiency anemia. Thus, iron continues to be of public health significance among women of childbearing age and pregnant women, who account for 26 percent of the general U. S. population.

Iron is also identified as a nutrient of public health significance in consensus reports. For example, Healthy People 2020 identified iron as a nutrient of public health significance among young children (1 to 4 years of age), women of childbearing age (12 to 49 years of age), and pregnant women, and announced an objective of a ten percent reduction in iron deficiency (using the body iron model) by the year 2020 (Ref. 104). Similarly, the 2010 DGA identified iron as a nutrient of concern among women capable of becoming pregnant and recommends choosing foods that supply heme iron, which is more readily absorbed by the body, additional iron sources, and enhancers of iron absorption such as vitamin C-rich foods (Ref. 6).

Given the importance of the role of iron in public health and continued significance of inadequate intakes and deficiency among women of childbearing age, a significant portion of the general healthy population, we tentatively conclude that iron is a nutrient of public health significance and its declaration continues to be necessary to assist consumers in maintaining healthy dietary practices. Therefore, consistent with the factors used for mandatory declaration of non-statutory nutrients (see section I.C.), we are not proposing any changes to the current requirement for declaration of iron on the Nutrition Facts label, as specified in § 101.9(c)(8)(ii).

c. Vitamin A--Vitamin A must be declared as a percent DV on the Nutrition Facts label (§ 101.9(c)(8)(ii)). In 1993, we required the declaration of vitamin A in nutrition labeling because (1) it was found in a limited number of foods within the food supply, and (2) a 1990 IOM labeling report (Ref. 95) identified vitamin A as a nutrient of potential public health significance and stated that certain subpopulations (children under 5 years of age) were still at risk of deficiency for this vitamin (58 FR 2079 at 2106). In response to the 2007 ANPRM, several comments recommended retaining the mandatory declaration of vitamin A, with some noting that the 2005 DGA identified it as a nutrient of concern (Ref. 36). Our analysis of intake data from NHANES 2003-2006 estimated that about 45 percent of the general U. S. population has usual vitamin A intakes from conventional foods below the EAR, and 34 percent have intakes from conventional foods plus dietary supplements below the EAR (table 1). However, the prevalence of vitamin A deficiency is not apparent. Only about 0.3 percent of those ages 6 years and older (excluding pregnant and lactating women) have a serum retinol concentration (a biomarker of vitamin A status) below 20 mcg/dL, a cutoff level that is used as an indicator of vitamin A deficiency (table 1) (Refs. 6 and 105). Because serum retinol levels are tightly regulated (homeostatically controlled) and do not always reflect total body status, using serum

vitamin A for assessment of vitamin A status of individuals may not be useful (Ref. 101). However, the distribution of serum retinol levels in a population plus the prevalence of individuals with serum retinol levels below a given cutoff point may offer a better picture of the vitamin A status of a population (Ref. 101). Based on the analysis of distribution of serum retinol (NHANES 2003-2006), and the prevalence of those below the cutoff of 20 mcg/dL (0.3 percent), we estimated that the prevalence of vitamin A deficiency in the general U. S. population is not apparent.

The IOM recognized that vitamin A deficiency is rarely seen in the healthy U. S. population (Ref. 105). Furthermore, the specific age and gender DRIs (EAR and RDA) set by the IOM were based on the amount of dietary vitamin A required to maintain adequate liver stores in well-nourished subjects, rather than on a specific adverse public health endpoint (Ref. 105). The DRIs represent an amount that will assure vitamin A reserves to cover periods of increased needs such as stress and low vitamin A intake (Ref. 105). In addition, the 2010 DGA does not include vitamin A among the list of nutrients of public health concern for the general U. S. population (Ref. 6).

We also considered whether any changes are necessary to the provision for voluntary declaration of the portion of vitamin A activity derived from  $\beta$ -carotene, including whether its mandatory declaration is appropriate, as suggested by a comment. One comment noted that  $\beta$ -carotene intake, in particular, needs to be increased, but the comment provided no further explanation. The IOM did not set DRIs for  $\beta$ -carotene and other carotenoids due to limited scientific data (Ref. 18). The only known function of provitamin A carotenoids (i.e.,  $\alpha$ -carotene,  $\beta$ -carotene, and  $\beta$ -cryptoxanthin, which can be converted into vitamin A (retinol) in the body) in humans is to act as a source of vitamin A in the diet (Ref. 18). Furthermore, there is no clear

evidence that suggests a protective association between dietary vitamin A or  $\beta$ -carotene and risk reduction of chronic diseases, such as cardiovascular disease and cancers (Ref. 105). In addition, evidence from large clinical trials suggests that  $\beta$ -carotene supplementation increases the incidence of lung cancer in a high-risk population (e.g., current or former smokers, asbestos workers) (Refs. 106 and 107). Further, the IOM introduced mcg of RAEs (retinol activity equivalents) as a new unit for expressing vitamin A activity to account for the reduced absorption for provitamin A carotenoids, including  $\beta$ -carotene (Ref. 105). This new unit, which would be the appropriate unit for declaring vitamin A on the Nutrition Facts label, takes into consideration vitamin A from all sources as well as the bioavailability of  $\beta$ -carotene and other provitamin A carotenoids (see section II.J.3.).

Our analysis demonstrates that, even though vitamin A intakes appear to be low, vitamin A deficiency based on an assessment of vitamin A status is rare in the U.S population. The IOM did not set a quantitative intake recommendation for vitamin A based on a public health endpoint. Thus, we tentatively conclude that vitamin A is no longer a nutrient of public health significance for the general U. S. population. Therefore, consistent with the factors for declaration of non-statutory nutrients (see section I.C.), we are proposing to amend 101.9(c)(8)(ii) to no longer require, but to permit voluntary declaration of vitamin A on the Nutrition Facts label. However, vitamin A declaration would remain mandatory when vitamin A is added as a nutrient supplement or claims are made about it on the label or in labeling of foods. We are also not proposing to change the current provision for voluntary declaration of the percent of vitamin A that is present as  $\beta$ -carotene, as specified in § 101.9(c)(8)(vi). We request comment about whether there is an appropriate alternative analysis to application of the factors in section I.C. regarding the mandatory declaration of vitamin A.

d. Vitamin C--Vitamin C must be declared as a percent DV on the Nutrition Facts label (§ 101.9(c)(8)(ii)). In 1993, we required the declaration of vitamin C because (1) a 1990 IOM labeling report (Ref. 95) identified vitamin C as a nutrient of potential public health significance and stated that certain subpopulations were considered at risk of deficiency (such as elderly individuals on inadequate diets and infants fed cow's milk exclusively) (58 FR 2079 at 2106), and (2) vitamin C was thought to play a role in promoting the intestinal absorption of non-heme iron, meaning that vitamin C in the same food as iron was considered to help prevent iron deficiency anemia, while excess vitamin C was considered to increase the risk of excessive iron absorption (55 FR 29487 at 29501, July 19, 1990). In response to the 2007 ANPRM about whether vitamin C is still a nutrient of public health significance, several comments recommended retaining the mandatory declaration of vitamin C, with some stating that vitamin C should be retained because it is a nutrient of concern identified by the 2005 DGA (Ref. 36), and is an enhancer of iron absorption for women of childbearing age.

Our analysis of NHANES 2003-2006 estimated that about 35 percent of the general U. S. population has usual vitamin C intakes below the EAR, from conventional foods only and 27.5 percent have intakes below the EAR from conventional foods and supplements (table 1). While the prevalence of inadequate intake is high, prevalence of vitamin C deficiency is not apparent in the U. S. population. Only about 6 percent of the general population had serum vitamin C concentrations below 11.4 micromoles ( $\mu\text{mol}$ )/L, a cutoff level that is used as an indicator of vitamin C deficiency (Ref. 97 p.534; Ref. 101). The EAR for vitamin C is based on estimates of body pool or tissue levels of vitamin C that are required for antioxidant protection with minimal urinary loss, not on a public health endpoint (Ref. 18).

The effects of vitamin C on risk of chronic diseases, such as cardiovascular disease or cancer, are not conclusive at this time (Ref. 18). We issued a letter of enforcement discretion on qualified health claims for vitamin C supplement intake and reduced risk of cancers, in which we concluded that there was no credible evidence on the risk reduction from vitamin C for most cancers (squamous cell cancer of the esophagus, colorectal, laryngeal, lung, oral cavity, pancreatic, pharyngeal, renal cell, and salivary gland cancers), and very limited evidence for an association between vitamin C supplement intake and gastric cancer (Ref. 108).

The 2010 DGA does not include vitamin C among the list of nutrients of public health concern for the general U. S. population (Ref. 6). However, the 2010 DGA recommends that women capable of becoming pregnant choose foods that are enhancers of iron absorption, such as vitamin C-rich foods (Ref. 6). While we agree that vitamin C enhances iron absorption, the prevalence of vitamin C deficiency in this subpopulation is not apparent. Only about 6 percent of this subgroup had serum vitamin C concentrations below 11.4  $\mu\text{mol/L}$  (table 1).

Based on the previous analysis and information, we tentatively conclude that while vitamin C intakes are low, vitamin C deficiency is uncommon and vitamin C is no longer a nutrient of public health significance for the general U. S. population. Therefore, consistent with the factors we consider for declaration of non-statutory nutrients (see section I.C.), we are proposing to amend § 101.9(c)(8)(ii) to no longer require, but to permit voluntary declaration of vitamin C on the Nutrition Facts label. However, vitamin C declaration would remain mandatory when vitamin C is added as a nutrient supplement or claims are made about it on the label or in labeling of foods. We request comment about whether there is an appropriate alternative analysis to the application of the factors in section I.C. regarding the mandatory declaration of vitamin C.

## 2. Essential Vitamins and Minerals That Are Voluntary

a. Vitamin D--The declaration of vitamin D content in nutrition labeling is voluntary, unless vitamin D is added as a nutrient supplement or claims are made about it (§ 101.9(c)(8)(ii)). In 1993, we determined that vitamin D is not of particular public health significance in the United States because the human requirement for vitamin D could be met with sufficient exposure to sunlight and milk and other foods that were fortified with vitamin D. As a result, deficiencies in this vitamin were very rare (58 FR 2079 at 2107). In response to the 2007 ANPRM about what, if any, other micronutrients are of public health significance, several comments recommended vitamin D for mandatory declaration citing vitamin D inadequacy; relationship of vitamin D to chronic disease risk (e.g., rheumatoid arthritis, multiple sclerosis, and cancers, such as prostate, breast, lung, colon, and colorectal cancers); and the 2005 DGA, which identified vitamin D as a nutrient of concern for certain subpopulations (e.g., older adults, people with dark skin, and those exposed to insufficient ultraviolet band radiation) (Ref. 36).

The IOM set age and gender specific DRIs (EAR and RDA) for vitamin D at a level that would achieve and maintain serum 25-hydroxy vitamin D (25(OH)D) concentrations above a defined level (40 to 50 nanomoles (nmol)/L) in order to maintain bone health (Ref. 22). Vitamin D has a role in bone health through calcium absorption and uptake by bones (Ref. 22). In addition, in 2008, we authorized a health claim for calcium and vitamin D intake and reduced risk of osteoporosis (§ 101.72), signifying vitamin D's critical role in the risk reduction of this chronic disease.

Vitamin D can be obtained through dietary sources, such as fish (e.g., salmon, rockfish, and tuna) and shellfish, which are the primary natural food sources of vitamin D. FDA affirmed certain uses of vitamin D food ingredients as Generally Recognized as Safe (GRAS) with

specific limitations as listed in § 184.1950. Under § 184.1(b)(2), an ingredient affirmed as GRAS with specific limitations may be used in food only within such limitations, including the category of food, functional use, and level of use. Any addition of the ingredient to food beyond the limitations set out in § 184.1950 requires either a food additive regulation or an amendment of § 184.1950. In this way, FDA can ensure that the vitamin D ingredients are added to food at safe levels. For detail on estimating dietary intake of substances in food, see FDA's Guidance for Industry: Estimating Dietary Intake of Substances in Food (Ref. 109). Under FDA regulations (§§ 172.380 (21 CFR 172.380) and 184.1950), vitamin D can be added in specific amounts to foods such as breakfast cereals, grain products and pastas, fluid milks and milk products, and calcium-fortified juices. As for any vitamin or mineral, when vitamin D is added to a food, the total amount per serving must be declared in the Nutrition Facts label. In addition to dietary sources of vitamin D from conventional foods and dietary supplements, vitamin D is synthesized in the skin following direct exposure to the sun. Therefore, sunlight exposure is an important source of vitamin D.

Serum concentration of 25(OH)D is widely considered as a biomarker of total vitamin D nutritional status and is recommended to be used for assessing vitamin D total exposure from all sources, including conventional foods, dietary supplements, synthesis from sun, and conversion of vitamin D from adipose stores in liver (Ref. 22). Our analysis of NHANES 2003-2006 data showed that about 18 percent of the U. S. population 4 years and older (excluding pregnant and lactating women) have serum 25(OH)D levels below the 40 nmol/L (a level set by IOM as equivalent to EAR), which indicates an increased risk of inadequate vitamin D exposure. NHANES data collection normally does not include serum levels in the northern regions of the United States in the winter months, when one would expect a lower serum vitamin D level.

Therefore, analysis of NHANES data may underestimate the prevalence of low serum vitamin D levels in the United States population. Analysis of NHANES 2005-2008 dietary data showed that, about 94 percent of the U. S. population have usual vitamin D intakes below the EAR from conventional foods only and 62 percent have intakes below the EAR from conventional foods and supplements (table 1). The IOM set the DRIs (e.g., EAR) assuming minimal sun exposure (Ref. 22).

Furthermore, approximately 24 percent of the U. S. population ages 4 years and older have serum 25(OH)D concentrations between 30 and 50 nmol/L, levels that indicate risk for inadequacy according to the IOM and CDC (Refs. 22 and 101). Approximately 32 percent of the U. S. population have serum 25(OH)D levels below 50 nmol/L (a level set by IOM as equivalent to RDA and associated with optimal benefit for nearly all the population) (Ref. 22). Also, about 8 percent have serum 25(OH)D levels below IOM's cutoff of 30 nmol/L and may be at increased risk of vitamin D deficiency. Vitamin D deficiency results in inadequate bone mineralization or demineralization of the skeleton including rickets, osteomalacia, and osteoporosis (Ref. 22). The 2010 DGA, too, highlighted vitamin D as a nutrient of concern for the U. S. population, in general, rather than for specific population groups alone (Ref. 6).

We do not agree with some comments that suggested that vitamin D intake should be mandatory on the label because of its relationship to disease risk reduction, generally. The IOM did not set DRIs for vitamin D based on its protective effect against diseases, such as cancers, cardiovascular disease, and diabetes, because the scientific evidence does not support a role other than that associated with bone health (Ref. 22).

In view of the benefits of adequate vitamin D intakes on bone health, reflected in the IOM's DRIs, data indicating inadequate intakes, poor vitamin D status, and high prevalence of

osteoporosis and osteopenia (discussed previously in the calcium section, (Refs. 98 and 99) among the general U. S. population, we tentatively conclude that vitamin D is a nutrient of "public health significance," as described in section I.C., and its mandatory declaration is necessary to assist consumers in maintaining healthy dietary practices. Therefore, consistent with the factors we consider for mandatory declaration of non-statutory nutrients (see section I.C.), we are proposing to amend § 101.9(c)(8)(ii) to require the mandatory declaration of vitamin D on the Nutrition Facts label. We request comment about whether there is an appropriate alternative analysis to the application of the factors in section I.C. regarding the mandatory declaration of vitamin D.

b. Potassium--The declaration of potassium content is voluntary, except when a claim is made about it (§ 101.9(c)(5)). In 1993, potassium did not meet our considerations for inclusion as a mandatory element of nutrition labeling because no quantitative intake recommendations were available in national consensus reports (58 FR 2079 at 2095). In response to our question in the 2007 ANPRM about what, if any, other micronutrients are of public health significance, several comments supported mandatory declaration of potassium on the Nutrition Facts label because the 2005 DGA identified it as a nutrient of concern (Ref. 36). One comment also pointed out that scientific evidence from three meta-analyses of over 30 clinical trials shows that high potassium intake is associated with reduced blood pressure in non-hypertensive and hypertensive individuals (Refs. 110 to 112).

Our analysis of data from NHANES 2003-2006 shows that the usual mean intakes of potassium from conventional foods only (2,644 mg/d) and from conventional foods plus dietary supplements (2,651 mg/d) are below the population-weighted AI of 4,622 mg/d. Where the mean usual intake is at or above the AI, we consider that there is probably a low prevalence of

nutrient inadequacy in the population assessed. However, where the mean usual intake is below the AI, the population's prevalence of inadequacy cannot be estimated (Ref. 96). Therefore, the likelihood of nutrient inadequacy cannot be estimated. Only about 1.9 percent of the general population has usual potassium intakes above the AI from conventional foods only and 2.4 percent has intakes above the AI from conventional foods plus dietary supplements (table 1), indicating that the adequacy of intakes is very low. In the absence of a sensitive biochemical indicator of potassium nutritional status, we could not consider biomarker data to inform the determination of prevalence of potassium deficiency. However, the IOM set age- and gender-specific AIs for potassium based on risk of chronic disease. The AI was set at a level that would maintain blood pressure, reduce the adverse effects of sodium chloride intake on blood pressure, and reduce the risk of recurrent kidney stones (Ref. 21). According to the CDC, about one out of three U. S. adults has high blood pressure (Ref. 113).

In 2000, a FDAMA notification for a health claim about potassium, blood pressure, and stroke was submitted to us under section 403(r)(2)(g) of the FD&C Act (Ref. 114). We did not object to the notification and this meant that manufacturers could include the following claim "Diets containing foods that are good sources of potassium and low in sodium may reduce the risk of high blood pressure and stroke," on the label or labeling of any food that meets the eligibility criteria described in the notification and meets the general requirements for health claims (§ 101.14(e)(6)). Thus, we recognize the importance of potassium in the risk reduction of these chronic diseases. The 2010 DGA also concluded that potassium is a nutrient of concern for the general U. S. population (Ref. 6).

In view of the benefits of adequate potassium intake in lowering blood pressure, reflected in IOM's DRIs, and data indicating low likelihood of potassium adequacy and high prevalence

of hypertension among the general population, we tentatively conclude that potassium is a nutrient of public health significance for the general U. S. population and its declaration is necessary to assist consumers in maintaining healthy dietary practices. Therefore, consistent with the factors we consider for mandatory declaration of non-statutory nutrients (see section I.C.), we are proposing to amend § 101.9(c)(8)(ii) to require the mandatory declaration of potassium.

### 3. Other Essential Vitamins and Minerals

Several other essential vitamins and minerals, in addition to vitamin D and potassium, may be declared on the Nutrition Facts label, i.e., vitamin E, vitamin K, vitamin B<sub>6</sub>, vitamin B<sub>12</sub>, thiamin, riboflavin, niacin, folate, biotin, pantothenic acid, phosphorus, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, and chloride. In response to the 2007 ANPRM about what, if any, other micronutrients are of public health significance, several comments recommended mandatory declaration of these voluntarily declared essential vitamins and minerals: Vitamin E, folate, vitamin B<sub>12</sub>, magnesium, and phosphorus. The reasons cited in comments included: (1) The 2005 DGA identification of these nutrients as nutrients of concern (Ref. 36); (2) the need to provide information to patients; (3) the need to heighten consumer awareness; and (4) the intakes of these nutrients are inadequate in the U. S. population or subpopulations (Ref. 47).

Based on FDA's analysis of available data using the factors we consider for mandatory and voluntary declaration of non-statutory nutrients (see section I.C.) and comments received on essential vitamins and minerals that are currently voluntarily declared, we are not proposing any changes to the current provisions for voluntary declaration (for detailed information and the analysis of each of the vitamins and minerals see Ref. 115. We reviewed data related to the

intake and status of nutrients where available standards allow for such calculations (table 1). Consistent with the factors (see section I. C.) , essential vitamins and minerals (with the exception of potassium and vitamin D discussed previously) that are voluntarily declared should continue to be permitted to be voluntarily declared (Ref. 115) . Therefore, we are not proposing any changes to the provisions for voluntary declaration of vitamin E, vitamin K, vitamin B<sub>6</sub>, vitamin B<sub>12</sub>, thiamin, riboflavin, niacin, folate, biotin, pantothenic acid, phosphorus, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, and chloride.

In addition, several comments recommended mandatory declaration of choline, which is currently not permitted to be declared on the Nutrition Facts label. Based on the factors we consider (see section 1.C) and comments that asked us to provide for its declaration on the Nutrition Facts label (Ref. 115), we tentatively conclude that the voluntary declaration of choline is consistent with the factors we consider for voluntary declaration (table 1) and, therefore, we are proposing to permit the voluntary declaration of choline on the Nutrition Facts label.

#### 4. Summary

In summary, based on an analysis of the factors FDA considered (as described in section I.C.), comments received, and other data and information set forth previously, FDA tentatively concludes that calcium, iron, vitamin D and potassium are nutrients of public health significance and their declarations on the Nutrition Facts label are necessary to assist consumers in maintaining healthy dietary practices. Calcium is considered a nutrient of public health significance due to the benefits of adequate calcium intake on bone health, and the relatively low intakes of calcium and the high prevalence of osteoporosis and osteopenia among the U. S. population. Iron is considered a nutrient of public health significance due to the continued inadequate intakes and deficiency (using relevant biomarker data) among women of childbearing

age, who comprise a significant portion of the general healthy U. S. population. Although the DRIs for iron were not based on a chronic disease risk, iron deficiency and low iron stores over time will lead to iron deficiency anemia, an advanced stage of iron deficiency. Anemia is associated with poor cognitive function, lower work performance, and low endurance in the general population; delayed psychomotor development in infants; and adverse pregnancy outcome. Vitamin D is considered a nutrient of public health significance due to the benefits of adequate vitamin D intake on bone health, data indicating inadequate intakes and status (both from total exposure (serum data) and dietary intake data), and the high prevalence of osteoporosis and osteopenia among the U. S. population. Adequate intake of vitamin D is essential for promoting calcium absorption in the gut and for maintaining adequate calcium levels in the blood and thus promoting bone health. Potassium is considered a nutrient of public health significance due to the benefit of adequate intake of potassium in lowering blood pressure, reducing the adverse effects of sodium chloride intake on blood pressure and reducing the risk of recurrent kidney stones, and due to data indicating a low likelihood of potassium adequacy and a high prevalence of hypertension among the general U. S. population.

Although we continue to consider, consistent with our rationale put forth in 1993, that a vitamin or mineral's public health significance should be the key factor in mandatory labeling (58 FR 2079 at 2106), the proposed vitamins and minerals of public health significance (i.e., potassium, calcium, vitamin D, and iron) and dietary fiber (listed on the label as a nutrient to increase) do represent various food groups. For example, potassium is found in most food groups, especially vegetables, fruits, and milk and milk products. Milk and milk products contribute substantially to calcium intake. Sources of heme iron include lean meat, poultry and seafood, while the non-heme sources of iron come from plants foods, such as beans, lentils and

spinach. Although vitamin D is mostly found in fortified foods in the United States, such as fluid milk and some milk products (e.g., yogurt), its natural sources include seafood. Dietary fiber is generally found in most fruits and vegetables, whole grains and beans.

The 2010 DGA recommends increasing the amount and variety of seafood in place of some meat and poultry (Ref. 6). As mentioned, fish/seafood is the primary source of naturally occurring vitamin D (Ref. 6). Data shows that fish/seafood only provides 9 percent of the total vitamin D intake in the United States (Ref. 116). Therefore, we tentatively conclude that the proposed mandatory declaration of vitamin D on the label would allow consumers to understand the relative significance of the contribution of vitamin D from natural food sources, in addition to fortified foods, in the context of the total daily diet and also is necessary to assist consumers in maintaining healthy dietary practices.

We are not aware of any unintended consequences of mandatory listing, in general, of vitamins and minerals. We invite comment, including the submission of data and information on whether the mandatory listing of vitamins and minerals somehow impacts food fortification practices. We invite comment on the proposed mandatory declaration of vitamin D, potassium, calcium and iron on the label, including how we consider the public health significance of each. We also invite comment on whether the presence of these nutrients presents concerns related to label space or the need for consumer education.

Table 1.--Prevalence of Adequacy and Inadequacy (From Conventional Foods and Water) and Total Intake (Conventional Foods, Water, and Supplement) and Status Biomarkers for Essential Vitamins and Minerals Among the U. S. Population, Ages 4 Years and Older (Excluding Pregnant and Lactating Women)<sup>1</sup>

		Usual Nutrient Intake <sup>2</sup>				Status Biomarkers	
Nutrients	Weighted EAR/AI <sup>3</sup>	% Below Weighted EAR <sup>4</sup>		% Above Weighted AI <sup>5</sup> (Mean Intake)		Biomarker Cutoff	
		Food	Food Plus Supplement	Food	Food Plus Supplement	Biomarker Cutoff	% Below Cutoff
Vitamins							
Choline (NHANES 2005-2008)	460 mg (AI)			10 (mean = 311 mg)	10 (mean = 312 mg)	NA	NA
Folate	304 mcg DFE	8.7	7.3			Serum folate < 2 ng/mL RBC folate < 95 ng/mL	0 0.26
						Women 12-49 yrs Serum folate < 2 ng/mL RBC folate < 95 ng/mL	0 0.36
Niacin <sup>6,7</sup>	11 mg NE	2.1	1.7			NA	NA
Riboflavin <sup>6,7</sup>	0.9 mg	1.5	1.3			NA	NA
Thiamin <sup>6,7</sup>	0.9 mg	5.6	3.8			NA	NA
Vitamin A	531 mcg RAE	45	34			Serum A < 20 mcg/dL	0.3 <sup>8</sup>
Vitamin B <sub>6</sub> <sup>6,7</sup>	1.1 mg	9.4	7.3			NHANES 2005-2006 < 20 nmol/L	10
Vitamin B <sub>12</sub>	1.9 mcg	2.3	2.2			Serum B <sub>12</sub> < 200 picograms (pg)/mL	2.0
	2 mcg	Women				19-50 yrs 51 yrs and older	0.7-2.5 3.3-5.2

Nutrients	Weighted EAR/AI <sup>3</sup>	Usual Nutrient Intake <sup>2</sup>				Status Biomarkers	
		% Below Weighted EAR <sup>4</sup>		% Above Weighted AI <sup>5</sup> (Mean Intake)		Biomarker Cutoff	% Below Cutoff
		Food	Food Plus Supplement	Food	Food Plus Supplement		
	(51 yrs and older)	51 yrs and older 6.4-7.5  Men 51 yrs and older 0.6-0.7					
Vitamin C	61 mg	35  Women 12-49 yrs 41	27.5  Women 12-49 yrs 30			Serum C < 11.4 µmol/L  Women 12-49 yrs	6.1 <sup>8</sup>  6.00
Vitamin D	10 mcg	93.7 (NHANES 2005-2008)	62 (NAHNES 2005-2008)			Serum 25 (OH)D: < 40 nmol/L 30-50 nmol/L < 30 nmol/L	17.6 24 8.3
Vitamin E	11 mg α- tocopherol	92	64			Serum E < 11.6 µmol/L	0.9 <sup>8</sup>
Vitamin K <sup>6,7</sup>	95 mcg (AI)			27.2 (mean = 82.9 mcg)	30.9 (mean = 88 mcg)	NA	NA

		Usual Nutrient Intake <sup>2</sup>				Status Biomarkers	
Nutrients	Weighted EAR/AI <sup>3</sup>	% Below Weighted EAR <sup>4</sup>		% Above Weighted AI <sup>5</sup> (Mean Intake)		Biomarker Cutoff	
		Food	Food Plus Supplement	Food	Food Plus Supplement	Biomarker Cutoff	% Below Cutoff
Minerals							
Calcium	885 mg	49	37			NA	NA
Copper <sup>6,7</sup>	0.7 mg	5.2	4.9			NA	NA
Iron (probability approach method) <sup>9</sup>	See footnote 3	3.5	3.3			NHANES 1999-2002 <sup>10</sup>	
						Serum ferritin < 15 mcg/L	8.3
						Ferritin model	6.5
						Anemia	1.9
		Women 12-49 yrs	Women 12-49 yrs			Women, 12-49 yrs NHANES 2003-2006:	
		11.2	10.4			Serum Ferritin < 15 mcg/L	14
						Body Iron model	10
						Ferritin Model	14.5
						Anemia	4.7
Iodine <sup>6,7</sup>	91 mcg	2.3 <sup>11</sup>	2.3			Urinary iodine NHANES 2007-2008:	
						<50 ng/mL <sup>12</sup>	8.7 <sup>8</sup>
						<100 ng/mL <sup>13</sup>	Median =

Nutrients	Weighted EAR/AI <sup>3</sup>	Usual Nutrient Intake <sup>2</sup>				Status Biomarkers	
		% Below Weighted EAR <sup>4</sup>		% Above Weighted AI <sup>5</sup> (Mean Intake)		Biomarker Cutoff	% Below Cutoff
		Food	Food Plus Supplement	Food	Food Plus Supplement		
							165 ng/mL
Magnesium	283 mg	56	53			NA	NA
Phosphorus	640 mg	3	2.6			NA	NA
Potassium	4,622 mg (AI)			1.9 (mean = 2,644 mg)	2.4 (mean = 2,654 mg)	NA	NA
Selenium <sup>6,7</sup>	43 mcg	1.4	1.1			NA	NA
Zinc <sup>6,7</sup>	7.7 mg	13.4	9.1			NA	NA

NA = Data is not available in NHANES; mg = milligrams; mcg = micrograms; DFE = Dietary folate equivalents; NE = Niacin equivalents; RAE = Retinol activity equivalents.

<sup>1</sup>All prevalence of nutrient adequacy or inadequacy and status biomarker data is based on NHANES 2003-2006 unless otherwise is reported. All data analysis are based on ages 4 years and older (excluding pregnant and lactating women), unless reported otherwise.

<sup>2</sup> Usual nutrient intake distributions from conventional foods or conventional foods plus supplements are determined using the National Cancer Institute statistical method for all nutrients except iron (see footnote 9 to this table and Ref. 48).

<sup>3</sup> Weighted Estimated Average Requirement (EAR) and Adequate Intake (AI) for all nutrients (except iron) are based on the U. S. population ages 4 years and older using U. S. Census Bureau, Population Projection for 2005, Middle Series Data (NP-D1-A) ([Ref. 48,117](#)). For iron, the published IOM tables (tables I-6 and I-7) of probability of iron requirement distribution were used (Ref. 100).

<sup>4</sup> EAR cut-point method used to compare usual nutrient intakes to the EAR to determine the prevalence of nutrient inadequacy.

<sup>5</sup> For nutrients with an AI, prevalence of nutrient adequacy was determined when mean usual nutrient intakes are at or above the AI or based on the percent of those above the AI.

<sup>6</sup> The Agency did not receive any comments for these nutrients (which voluntary declaration is permitted) in response to the 2007 ANPRM. In addition, dietary intake or status biomarker data were not provided in the NHANES database for chromium, biotin, pantothenic acid, molybdenum, manganese and chloride and, therefore, these nutrients are not listed in this table.

<sup>7</sup> The DRIs for these nutrients were not based on a public health endpoint (e.g., chronic disease).

<sup>8</sup> Ages 6 years and older.

<sup>9</sup> Probability approach method was used to determine the prevalence of nutrient inadequacy for iron. The PC-SIDE software developed by the Iowa State University was used to determine the usual intake distribution for iron.

<sup>10</sup> Iron deficiency based on the ferritin model is calculated using 2 out of 3 cutoffs of iron deficiency variables (transferrin saturation, serum ferritin, and erythrocyte protoporphyrin). Iron deficiency based on the iron body model is calculated from the log ratio of transferrin receptor to ferritin. Anemia was based upon iron deficiency criteria (ferritin model) and a low hemoglobin level. NHANES 1999 -2002 did not measure transferrin receptor, therefore body iron model could not be analyzed for the general population (ages 4 years and older). NHANES 2003-2006 did not measure all iron biomarkers for all ages (4 years and older), thus serum ferritin, body iron model or ferritin model could not be analyzed for all ages during this time period.

<sup>11</sup> Iodine nutrient intake data are calculated from the Total Diet Study 2003-2008 and intake data are calculated from NHANES 2003-2008 ([http://www.nutrientdataconf.org/PastConf/NDBC36/7-3\\_Juan\\_NNDC2012.pdf](http://www.nutrientdataconf.org/PastConf/NDBC36/7-3_Juan_NNDC2012.pdf)).

<sup>12</sup> One criterion for iodine adequacy is that not more than 20 percent be below the urinary iodine cutoff of 50 ng/mL (indicator of moderate deficiency) (Ref. 118).

<sup>13</sup> WHO categories for median urinary iodine concentrations are widely used to define iodine intake (Ref. 118). Median intake levels below 100 ng/mL may indicate mild iodine deficiency.

## I. Reference Daily Intakes for Vitamins and Minerals

### 1. Need to Update RDIs

RDIs used to calculate the percent DVs for vitamins and minerals that are required or permitted to be declared on the Nutrition Facts label are codified in § 101.9(c)(8)(iv). We established the RDIs in 1993 and in 1995, and explained our rationale and relevant considerations during those rulemakings (58 FR 2079; 60 FR 67164; see also Ref. 1). We noted specifically that the purpose of establishing RDIs for vitamins and minerals was to provide "label reference values" intended to help consumers to understand nutrient levels in the context of the total daily diet, to compare foods, and to plan general diets (58 FR 2206 at 2213). We recognized that nutritional needs vary considerably among consumers, but noted that no other viable option existed other than a single reference value (58 FR 2206 at 2213). Thus, RDIs are intended as general food labeling reference values and are not intended to represent dietary allowances for individuals (55 FR 29476 at 29478). While RDIs are not precise values for certain age and sex groups, they function as an overall population reference to help consumers judge a food's usefulness in meeting overall daily nutrient requirements or recommended consumption levels and to compare nutrient contributions of different foods (55 FR 29476).

IOM reports published since 1997 provide new information for our use in reconsidering the RDIs. The DRIs revised many of the previously set RDAs for vitamins and minerals. Four types of DRIs are relevant to the discussion on RDIs for vitamins and minerals: EAR, RDA, AI, and UL. We describe each of these DRIs in section I.B.2. According to the new DRI reports, some nutrients that had RDAs now have an AI because it was determined that data were not sufficient to set a new RDA (e.g., vitamin K), whereas others that had ESADDIs now have either an RDA (copper and molybdenum) or an AI (manganese, fluoride, and chromium).

The IOM Labeling Report (Ref. 25) recommended that FDA use a population-weighted EAR or, in its absence, a population-weighted AI as the basis for establishing DVs for vitamins and minerals. In developing these recommendations, the IOM indicated that the reference values on food labeling are to enable consumers to compare the nutrient content of different food products and to determine the relative contributions of a food to an overall health promoting diet. The IOM Labeling Committee did not consider that the information in nutrition labeling is used to plan individual diets. The IOM recommended that the DVs should be based on a population-weighted value of the EAR for the different life stage and gender groups so that the DVs are representative of the various population groups in proportion to their contribution to the overall population. A DV defined this way would represent a central value of the requirements of the population, with individual requirements varying around this value. The IOM Labeling Committee further stated that the EAR represents the most accurate representation of the true contribution of food to total nutrient needs of the general population, whereas the RDA provides an exaggerated impression of Americans' daily needs and, thus, would systematically under-represent the true contribution of an individual food to many consumers' needs. The IOM Labeling Committee concluded that the EAR is the best estimate of any given individual's requirements, because the EAR is the median of the estimated distribution of requirements for a particular life stage and gender group. Therefore, the IOM Labeling Committee stated that setting the DV at the EAR is most likely to help individuals understand nutrition information about vitamins and minerals on the Nutrition Facts label in the context of their total daily diet. The IOM Labeling Committee further recommended that, in the absence of an available EAR, a population-weighted AI should be used as the basis for a DV.

The IOM Dietary Planning Report noted that intake goals (i.e., RDAs) should be translated into dietary plans to help individuals choose foods that will make up a healthful diet. The IOM Dietary Planning Report gave several examples of dietary plans such as the Nutrition Facts label, United States Food Guide Pyramid and the Dietary Guidelines for Americans that are intended to help consumers choose foods that are part of a healthful diet (Ref. 26). This report noted that when food guides such as those mentioned previously are used, reference standards for nutrients, such as RDAs, are implicitly used in planning individual diets (Ref. 26). The recommendations in the IOM Labeling Report and the IOM Dietary Planning Report have been the subject of much debate in the scientific community, and several review articles about the basis for selecting the DRI values that are most appropriate for setting DVs (i.e., RDIs) have been published in scientific journals (Refs. 119 to 126).

The 2007 ANPRM asked for public comment on whether the DV should be based on an EAR or RDA; how AIs should be used for determining DVs for vitamins and minerals without an EAR or RDA; and whether DVs should be based on a population-coverage or population-weighted approach. We received several comments both on the overall approach for setting the RDIs and on the DRIs for specific vitamins and minerals (Ref. 47).

We tentatively conclude that the existing RDIs for vitamins and minerals should be revised based on the DRIs set by the IOM that reflect the most current science regarding nutrient requirements. Our consideration of the DRIs, relevant recommendations, and comments received in updating the RDIs is presented in this document.

## 2. Approach to Setting RDIs: EAR Versus RDA

The percent DV advises the consumer how much of the recommended intake of that nutrient is provided by the food (58 FR 2206 at 2213). The DV for the nutrient, on which the

percent DV declaration is based, is not to be interpreted as a precise recommended intake level for an individual; it is for use as a general guide or reference value that can help the consumer judge a food's usefulness in meeting overall daily nutrient requirements or recommended consumption levels and to compare nutrient contributions of different foods (55 FR 29476). We established the RDIs for vitamins and minerals based primarily on RDAs, and using other available recommendations for those vitamins and minerals for which an RDA was not established (55 FR 29476; 58 FR 2206; 60 FR 67164). Overall, comments to the 2007 ANPRM supported continuing to use the RDA as the basis for the DVs for vitamins and minerals, whereas some other comments supported using the EAR instead (Ref. 47).

Considering the purpose of the DV, and for the reasons explained in this document, we tentatively conclude that RDAs, when available, continue to provide the most appropriate basis for establishing RDIs. RDAs are available for calcium, copper, folate, iodine, iron, magnesium, molybdenum, niacin, phosphorus, riboflavin, selenium, thiamin, vitamins A, B<sub>6</sub>, B<sub>12</sub>, C, D, and E, and zinc (Refs. 16 to 19,22).

The EAR, by definition, is the median requirement that is most likely to be close to an individual's actual needs within a particular life stage and gender group, with the needs of half of the individuals within that group falling above or below the EAR. The EAR is a quantitative intake recommendation that is used to derive target nutrient intake goals for the planning of diets for groups, but is not used as a target intake goal for individuals. Examples of planning for groups include planning diets in an assisted living facility for senior citizens or planning menus for a school nutrition program (Ref. 26). However, the EAR is not intended to be a target intake level for individuals because an individual does not know how their needs relate to the EAR. While the RDA may not be the best estimate of any given individual's nutrient requirement,

which is usually unknown, the RDA was developed as a target intake level for individuals and is designed to meet the nutrient needs of practically all (97 to 98 percent) individuals within a life stage and gender group. Therefore, if the RDI were to be based on the EAR, the RDI would not meet the daily nutrient requirements for some consumers and understate target intake levels. In contrast, an RDI that is based on a RDA would meet the daily nutrient requirements for the majority of all individuals 4 years of age and older. As we explained during the NLEA rulemaking, while RDIs are not precise values for specific age and sex groups, they function as an overall population reference to help consumers judge a food's usefulness in meeting overall daily nutrient requirements or recommended consumption levels and to compare nutrient contributions of different foods (55 FR 29476). An RDI based on the RDA would mean that a product with 100 percent of the DV would have a higher probability of meeting an individual's nutrient needs than if the RDI was based on the EAR.

In addition, consumers have indicated that they use the label, among other things, to make dietary judgments about a food and to plan meals. Our 2008 Diet and Health Survey reported that, among consumers who use the label when they buy a product for the first time, 62 percent often or sometimes use the label to help in meal planning; 85 percent often or sometimes use the label to get a general idea of the nutritional content of the food; and 90 percent often or sometimes use the label to see how high or low the food is in things like calories, salt, vitamins, or fat (Ref. 41). A series of surveys conducted by the International Food Information Council over the past several years also showed that approximately 65 percent of respondents used the Nutrition Facts label to decide whether to purchase or consume a food, and different individuals focus on different aspects of the label (e.g., calories, fat, or sodium) (Refs. 127 to 130).

We recognize that the recommendations of the 2003 IOM Labeling Report (Ref. 25) differ from the conclusions of the 2003 IOM Planning Report (Ref. 26). The IOM Labeling Report recommends using the EAR as the basis for developing DVs, whereas the IOM Planning Report indicated that the RDAs are appropriate targets for nutrient intakes for individuals. Inadequate intakes of some nutrients continue to be of public health significance, as noted by the 2010 DGA, which identified potassium, calcium, and vitamin D as nutrients of public health concern for general U. S. population and iron, folic acid, and vitamin B<sub>12</sub> for certain segments of the population (Ref. 6). Based on these concerns of inadequate nutrient intakes, we find that the IOM Dietary Planning Report discussion supports the use of RDAs as the basis for establishing reference values for the purposes of food labeling. We continue to believe that given the greater coverage provided by the RDAs compared to the EARs, more individuals who use the percent DV information to select foods, compare foods, or plan diets will have greater assurance that their nutrient needs are being met (58 FR 2206 at 2213). RDAs and AIs, not EARs, are also cited in both the 2010 DGA and the USDA's Food Patterns, which were formerly known as the MyPyramid Food Patterns (Refs. 6 and 131). It is important to reiterate, however, that the RDIs are not the same as RDAs. The RDAs are recommended intake levels set for different age and gender groups, whereas the RDIs are intended to provide an overall population reference value for use in calculating the percent DV for the food label that can help consumers understand the nutritional content of foods in the context of the total daily diet (55 FR 29476 at 29481 and 58 FR 2206 at 2213).

Finally, we considered the potential for the RDIs to influence the vitamin or mineral content of foods, as suggested by several comments (Ref. 47). We are not persuaded that using an EAR will promote rational fortification and that using the RDA as the basis for the RDI will

lead to overconsumption of vitamins and minerals, as was suggested by a comment (Ref. 47). FDA's principles of rational fortification are expressed in our fortification policy (§ 104.20). The addition of nutrients to foods is also governed by the requirements established in food standards of identity (21 CFR parts 130 to 169), nutrition quality guidelines (21 CFR part 104), substitute food regulations (§ 101.3(e)), and relevant specifications in food additive and food substance regulations (for example, folic acid (§ 172.345) and vitamin D (§§ 184.1950 and 172.380)). Consistent with our previous position (58 FR 2206 at 2210), we acknowledge that some manufacturers may fortify products to a specific percentage of the DV (e.g., 25 percent) and, to the extent this practice continues, nutrient levels in these foods would be affected by updated RDI values. Changing the basis from the current RDA approach to EARs would lower RDIs for many important nutrients. Regardless of whether the basis for the RDI is the RDA or EAR, manufacturers must comply with relevant regulations, and we urge them to follow the principles stated in our fortification policy. With respect to the concern for risk of excessive intakes of vitamins and minerals, we conducted a thorough analysis of available data to determine whether intakes of vitamins and minerals from both foods and dietary supplements exceed established ULs. An analysis of NHANES (2003-2006) data showed that usual total nutrient intakes (from both conventional foods and dietary supplements) at the 90th percentile do not exceed the ULs for most vitamins and minerals at any age group, except for zinc intake, vitamin A (preformed), iodine intake and folic acid intake among children 4 to 8 years (Ref. 132).

While there were a few exceptions, we have determined that such intakes are not of public health significance, and for some nutrients, are not a result of discretionary fortification. Therefore, we do not consider that the existing approach of using RDAs as the basis for RDIs

leads to widespread overconsumption of vitamins and minerals. Moreover, about half of the proposed RDIs decrease when compared to the current RDIs (table 2) because many of the new RDAs and AIs established by the IOM are now lower than previously set RDAs or ESADDIs. Most of the RDIs proposed in this rulemaking that would increase (i.e., calcium, vitamin D, dietary fiber, and potassium) have also been proposed by FDA to be nutrients of public health significance for the general U. S. population (see section II.H.). Furthermore, none of the RDIs proposed in this rulemaking exceed the ULs for children 4 to 8 years of age (see tables 11a and 11b of the 2007 ANPRM).

Therefore, we tentatively conclude that RDAs, when available, provide the most appropriate basis for establishing RDIs. Using corresponding RDAs, proposed § 101.9(c)(8)(iv) would update the RDIs for calcium, copper, folate, iodine, iron, magnesium, molybdenum, niacin, phosphorus, riboflavin, selenium, thiamin, vitamins A, B<sub>6</sub>, B<sub>12</sub>, C, D, and E, and zinc, as shown in table 2. We request comment on our analysis and request data and factual information, including any additional data on what role, if any, the basis of the DV (EAR or RDA) has in consumption of nutrients above the UL and in discretionary fortification of foods.

### 3. Approach to Setting RDIs: Adequate Intake

We consider that, in the absence of RDAs, AIs represent the best estimate of adequate daily nutrient intake level based on available science and, as such, they provide an appropriate basis for selecting RDIs for those vitamins and minerals where available data are insufficient to determine RDAs. While the prevalence of inadequacy of a nutrient with an AI cannot be determined, AIs, like RDAs, are goals for nutrient intakes and AIs are expected to meet the nutrient needs of most healthy people. The IOM noted that usual individual intakes for a nutrient that are equal to or above the AI can be assumed adequate (Ref. 25). We acknowledge that there

is more uncertainty with an AI than an EAR or RDA. However, in the case of nutrients without established RDAs, AIs reflect the most current scientific recommendations for intake (Ref. 25).

Moreover, using the AIs (where RDAs are not available) would ensure consistency in the basis of setting RDIs. We agree with comments to the ANPRM that RDIs for vitamins and minerals and consequently, percent DVs declared on the label, should have comparable meanings in order to enable consistent use. RDIs should not be based on average requirements (i.e., EAR) for some nutrients, but goals for intakes (i.e., RDAs) for others. AIs, in the absence of RDAs, would provide uniformity in setting RDIs for vitamins and minerals based on goals for their intakes. Most of the comments in response to the 2007 ANPRM supported the AI as the basis for the DV for those nutrients for which no EARs or RDAs have been established (i.e., biotin, chloride, choline, chromium, manganese, pantothenic acid, potassium, and vitamin K) (Ref. 47).

Therefore, we tentatively conclude that AIs provide an appropriate basis for selecting RDIs for those vitamins and minerals where available data are insufficient to determine RDAs. Accordingly, we are proposing to use AIs to set the RDIs for biotin, chloride, choline, chromium, manganese, pantothenic acid, potassium, and vitamin K.

#### 4. Approach to Setting RDIs: Tolerable Upper Intake Level

The UL is the highest average daily intake level likely to pose no risk of adverse health effects for nearly all people in a particular group. As intake increases above the UL, potential risk of adverse effects may increase (Ref. 96)). The UL can be used to estimate the percentage of the population at potential risk of adverse effects from excess nutrient intake (Ref. 25).

However, the UL is not intended to be a recommended level of intake for vitamins and minerals where excess intake is not a concern, as there is generally (with the exception of folate in the

prevention of neural tube defects) no established benefit for consuming amounts of nutrients above the RDA or AI (Ref. 96). Therefore, we do not consider the UL to be an appropriate basis for setting RDIs. However, as the IOM noted, ULs can be used to plan diets to ensure usual intakes of vitamins and minerals are below the UL for individuals or to plan diets for groups to minimize the proportion of the population at risk of excess nutrient intake (Ref. 25).

Therefore, we tentatively conclude that the UL does not provide an appropriate basis for establishing RDIs for vitamins and minerals. As noted previously (sections II.I.2. and II.I.3.), we tentatively conclude that the RDAs and, for nutrients where an RDA has not been established, AIs are the most appropriate quantitative intake recommendations for setting RDIs that can help consumers to plan general diets and understand the nutritional content of the foods they buy in the context of the total daily diet.

#### 5. Approach to Setting RDIs: Population-Weighted Versus Population-Coverage

As discussed in the 2007 ANPRM, we set the RDIs based on a population-coverage approach, after concluding that this approach was more appropriate than a population-weighted approach, in part, so that vulnerable or at-risk groups would be sufficiently covered by the DV (72 FR 62149 at 62150). In determining an approach for setting RDIs in this proposed rule, we considered recommendations of current consensus reports, scientific review articles, and comments to the 2007 ANPRM. We presented a comparison of potential RDIs based on the various established DRIs and applying the population-coverage versus population-weighted approaches (see tables 11A and 11B of the 2007 ANPRM). As discussed in this document, we tentatively conclude that RDIs for vitamins and minerals should continue to be based on a population-coverage approach, using the highest RDA and, where an RDA has not been established, the highest AI.

We continue to agree with the rationale we set forth in 1993 that the population-coverage approach would sufficiently cover the vulnerable or at-risk groups (58 FR 2206 at 2211). Using the highest age and gender group RDA/AI value (i.e., a population-coverage approach) would avoid a higher risk of nutrient inadequacy among certain segments of the population because such a value is not derived from averaging the requirements for populations with lower needs (children and elderly) and those with greater needs (adolescents or adults). While incidences of deficiency diseases, such as pellagra, are now rare, intakes and status biomarkers of certain nutrients continue to be inadequate and of public health significance (see section II.H.). Although, for some nutrients, the population-coverage RDA approach would result in RDIs that are higher than the nutrient requirements for some consumers, RDA, by definition, is the target intake goal for nutrient intakes for individuals. In addition, as noted by one comment, unlike the population-weighted approach, the population-coverage approach would not be susceptible to changes in age demographics of the population. Therefore, any future revisions to RDIs would be based primarily on new scientific data related to nutrition or new dietary recommendations, and we would not need to revise RDIs solely based on the availability of new census data.

We also considered concerns that the population-coverage approach may lead to excessive intakes of nutrients. As in the case of the RDA approach (discussed previously), we find such concerns unfounded. Intakes of vitamins and minerals generally do not exceed the ULs under current RDIs that are based on a population-coverage RDA approach. In a few instances where total usual intakes of vitamins and minerals by children 4 to 8 years exceed corresponding ULs, we have determined that such intakes are not of public health significance, and for some nutrients, are not as a result of fortification (see accompanying Ref. 115). Furthermore, because many of the new RDAs and AIs established by the IOM are now lower

than previously set RDAs or ESADDIs, the RDIs based on a population-coverage RDA for many nutrients will decrease (see table 2). We consider that, from a public health perspective, it is more important for the DV of vitamins and minerals to cover the intake needs of most consumers than it is for certain age and gender groups to be covered by the DV based on their proportion of the overall population. We are also not aware of any data indicating that use of a population-coverage approach versus a population-weighted approach results in increases in nutrient consumption. Therefore, we tentatively conclude that the population-coverage approach using the highest RDA or, in its absence, the highest AI continues to provide an appropriate basis for setting RDIs for vitamins and minerals. We are proposing to amend § 101.9(c)(8)(iv) to update RDIs as presented in table 2.

#### 6. Declaration of Absolute Amounts of Vitamins and Minerals

Currently, mandatory nutrients and, when declared, voluntary nutrients must be declared by their absolute amounts in weight on the Nutrition Facts label, except for vitamins and minerals (other than sodium and potassium) (see § 101.9(d)(7)(i)). Thus, except when the linear label format is used (§ 101.9(j)(13)(ii)(A)(2)), listings for sodium and potassium (when declared) appear above the third bar and include both weight amounts and percent DVs, while vitamins A and C, calcium, and iron appear below the third bar and include percent DVs only. In the case of dietary supplements, both the quantitative amount by weight and percent DV (if available) are required to be declared on the Supplement Facts label (§ 101.36(b)(2)(ii) and (iii)). The 2007 ANPRM invited comment on whether the absolute amounts (e.g., grams or milligrams) of mandatory and voluntary vitamins and minerals should be included on the Nutrition Facts and Supplement Facts labels (72 FR 62149 at 62170). Most comments supported including the absolute amounts of these nutrients in addition to the requirement of listing percent DVs.

Research suggests that consumers, in general, and physicians who prescribe nutrient supplements for specific medical reasons have difficulty understanding how percent DVs relate to the absolute amounts of nutrients listed on the Nutrition Facts label (Ref. 133). More recently, in a report on labeling and fortification, the IOM recommended listing both absolute amounts (e.g., mg/serving) and percent DVs to assist consumers who have difficulty understanding how to interpret the percent DV declaration (Ref. 25). This IOM report also stated that absolute amounts declaration for all micronutrients would maintain consistency in how nutrients are declared on the Nutrition Facts label.

Based on the IOM's recommendation, research findings, and comments received, we are proposing to require that, similar to the requirement for dietary supplements (§ 101.36(b)(2)(i)(A)), all vitamins and minerals declared on the Nutrition Facts label must include their quantitative amounts (in addition to the requirement for corresponding percent DV declaration) (proposed § 101.9(c)(8)). We request comments on this tentative conclusion, and seek input on the appropriate placement of the quantitative amounts of nutrients on the Nutrition Facts label.

Further, with the proposed requirement for declaration of absolute amounts of vitamins and minerals, it is necessary to establish when a vitamin or mineral is present in an insignificant amount as well as increments for declaration of the quantitative amounts of vitamins and minerals on the Nutrition Facts label. In determining requirements for vitamins and minerals present in insignificant quantities, as well as increments for declared vitamins and minerals, we looked to requirements that have already been established for declaration of quantitative amounts of sodium and potassium, vitamins and minerals declared on the Supplement Facts label, and percent DVs.

Quantitative amounts in milligrams may currently be listed on the Nutrition Facts label for only two minerals: Sodium, a mandatory nutrient (§ 101.9(c)(4)) and potassium (§ 101.9(c)(5)), which may be voluntarily declared on the Nutrition Facts label. We require in § 101.9(c)(4) and (c)(5) that when a serving contains less than 5 mg of sodium or potassium, the value shall be declared as zero; when a serving contains 5 to 140 mg of sodium or potassium, the declared value shall be rounded to the nearest 5 milligram increment; and when a serving contains greater than 140 mg of sodium or potassium, the declared value shall be rounded to the nearest 10 mg increment. We are now proposing to establish an RDI for potassium. Since potassium will now have an RDI, rather than a DRV, we are proposing to remove the specific requirements for the declaration of potassium in § 101.9(c)(5), and replace the section with requirements for the declaration of fluoride. Requirements for the declaration of quantitative amounts of other nutrients with an established RDI discussed in this document will apply to potassium, if finalized.

The quantitative amounts by weight per serving of vitamins and minerals are also required to be declared on the Supplement Facts label (§ 101.36(b)(2)(ii)). The amounts of vitamins and minerals, excluding sodium and potassium, that are declared on the Supplement Facts label are the amount of the vitamin or mineral included in one serving of the product, using the units of measurement and levels of significance given in § 101.9(c)(8)(iv). Section 101.36(b)(2)(ii)(B) also specifies that for declaration of vitamins and minerals on the Supplement Facts label, zeros following decimal points may be dropped, and additional levels of significance may be used when the number of decimal places indicated is not sufficient to express lower amounts (e.g., the RDI for zinc is given in whole mg, but the quantitative amount may be declared in tenths of a mg).

For conventional foods, FDA specifies in § 101.9(c)(8)(iii) that the percent DV declaration for vitamins and minerals present at less than 2 percent of the RDI is not required for nutrition labeling, but may be declared as zero or by the use of an asterisk (or other symbol) that refers to another asterisk (or symbol) that is placed at the bottom of the table and that is followed by the statement "Contains less than 2 percent of the Daily Value of this (these) nutrient (nutrients)." Alternatively, the statement "Not a significant source of (listing the vitamins or minerals omitted)" may be placed at the bottom of the table of nutrient values.

For the purpose of determining when a vitamin or mineral is present in an insignificant amount, we tentatively conclude that the cutoff used for declaration of percent DV of less than 2 percent of the RDI (§ 101.9(c)(8)(iii)) can reasonably be applied to the declaration of quantitative amounts of vitamins and minerals on the Nutrition Facts label. We find that, if a product contains less than 2 percent of the RDI per serving, it is appropriate to express the declared vitamin or mineral quantitative amount as zero. The manufacturer may choose to use an asterisk (or other symbol), instead of a declaration of zero, that refers to another asterisk (or symbol) placed at the bottom of the table and that is followed by the statement "Contains less than 2 percent of the Daily Value of this (these) nutrient (nutrients)." Alternatively, the statement "Not a significant source of (listing the vitamins or minerals omitted)" ("not a significant source" statement) may be placed at the bottom of the table of nutrient values.

As previously discussed, manufacturers have the option of using an asterisk (or symbol), instead of a declaration of zero, that directs the consumer to a statement indicating that the product is not a significant source of certain vitamins or minerals found at the bottom of the table of nutrient values when the calculated percent DV is less than 2 percent. We are concerned that it may be confusing to consumers if the manufacturer chooses to declare the quantitative amount

of a vitamin or mineral as zero, and also chooses to use an asterisk referring the reader to a statement at the bottom of the label instead of in the percent DV column on the Nutrition Facts label. Therefore, we are proposing to require that, when a product contains less than 2 percent of the RDI for a vitamin or mineral, the manufacturer must declare the quantitative amount of the vitamin or mineral and the percent DV in the same manner. For example, if a serving of the product contains less than 2 percent of the RDI for calcium, both the quantitative amount and the percent DV for calcium may be listed as zero or an asterisk (or symbol) directing the consumer to a statement at the bottom of the label may be used in place of both the quantitative amount and the percent DV declaration for calcium.

We see no reason to provide different declaration increments for the Nutrition Facts label than those that have already been established for the declaration of quantitative amounts of vitamins and minerals on the Supplement Facts label in § 101.36(b)(2)(ii). Therefore, we tentatively conclude that, as with the declaration of quantitative amounts of vitamins and minerals on the Supplement Facts label, the levels of significance given in § 101.9(c)(8)(iv) should be used. Zeros following decimal points may be dropped, and additional levels of significance may be used when the number of decimal places indicated is not sufficient to express lower amounts (e.g., the RDI for zinc is given in whole mg, but the quantitative amount may be declared in tenths of a mg).

We acknowledge that for some vitamins and minerals with RDIs that contain three or four digits (e.g., phosphorous has a proposed RDI of 1,250 mg), a difference of 1 mg per serving may not be meaningful in terms of health impacts. We request comment on whether quantitative amounts for nutrients with RDI values that contain three or four digits should be rounded, what

the rounding increments should be, and data to support suggested rounding increments for such vitamins and minerals.

## 7. Issues Concerning Specific Vitamins and Minerals

In this section, we address issues related to RDIs for specific vitamins and minerals, including those received in comments to the 2007 ANPRM. We discussed the declaration of these vitamins and minerals in section II.H. (and in accompanying Ref. 115).

a. Vitamin K--There are three general forms of vitamin K: Phylloquinone (vitamin K<sub>1</sub>), menaquinone (vitamin K<sub>2</sub>), and menadione (vitamin K<sub>3</sub>). For labeling purposes, there is no specific definition for vitamin K. The AIs for vitamin K are based on median intakes from NHANES data, which specifically represents the intake of phylloquinone, the major form of vitamin K in the diet (Ref. 134). The AI for vitamin K does not account for the intake of menaquinone or menadione because (1) NHANES data only includes phylloquinone content of foods, (2) the contribution of menaquinones, which can be produced by bacteria in the gut, to the maintenance of vitamin K status has not been established, and (3) menadione is a synthetic form of vitamin K that can be converted to a form of menaquinone in animal tissues. Because the AI for vitamin K is specific to phylloquinone, our proposed RDI for vitamin K, 120 mcg in proposed § 101.9(c)(8)(iv), that is based on the AI pertains only to phylloquinone.

b. Chloride--The RDI for chloride of 3,400 mg/d (§ 101.9(c)(8)(iv)) was established in 1995 and is based on the midpoint of the range (1,700 to 5,100 mg/d) of the ESADDI set in the 1980 RDA report (Ref. 135; 59 FR 427). The RDI for chloride is proportional to the DRV for sodium, considering that chloride losses tend to parallel losses of sodium and almost all dietary chloride comes from sodium chloride (60 FR 67164). The IOM set AIs and ULs for chloride on an equimolar basis to the AI and UL for sodium (Ref. 10). The 2007 ANPRM requested

comment on whether (1) the DV for chloride should continue to be an RDI, or should be a DRV like the current DV for sodium and (2) the DV for chloride should be based on the same DRI (AI versus UL) as used to set a DV for sodium.

A few comments supported setting a DRV for chloride on an equimolar basis to the UL for sodium. We disagree because the UL for chloride was not based on adverse effects associated with excess intake of chloride. Furthermore, the UL was not based on a public health endpoint specific to chloride intake, which is a basis for setting a DRV. Because chloride is an essential mineral and has age- and gender-specific AIs, we tentatively conclude that chloride should remain a RDI and be based on population-coverage AI (see section II.I.5.). Therefore, we are proposing to set an RDI for chloride using the population-coverage AI of 2,300 mg/d (proposed § 101.9(c)(8)(iv)).

c. Potassium--The DRV of 3,500 mg/d for potassium was established based on its beneficial health effects (e.g., reduction in blood pressure) (55 FR 29487 at 29500). We established a DRV rather than an RDI because an RDA for specific age and gender groups was not established at that time. In 2005, the IOM established age- and gender-specific AIs for potassium based on data showing that potassium lowers blood pressure, blunts the adverse effects of sodium chloride intake on blood pressure, reduces the risk of recurrent kidney stones, and possibly decreases bone loss (Ref. 136). Because potassium is an essential mineral and age- and gender-specific AIs are available, we tentatively conclude that an RDI should be established in place of the DRV. Therefore, using the population-coverage AI, we are proposing to establish an RDI for potassium of 4,700 mg/d (proposed § 101.9(c)(8)(iv)).

d. Choline--FDA regulations do not establish a reference value for choline. In 1998, the IOM established age- and gender-specific AIs for choline based on intakes necessary to maintain

liver function (Ref. 137). In 2001, we received a FDAMA notification under section 403(r)(2)(G) of the FD&C Act for the use of certain nutrient content claims for choline (Ref. 138). The FDAMA notification identified the DV for choline as 550 mg, which was based on the population-coverage AI for choline. Because the IOM established age- and gender-specific AIs for choline, we tentatively conclude that an RDI should be established. Thus, we are proposing in § 101.9(c)(8)(iv) to set an RDI of 550 mg for choline based on the population-coverage AI.

e. Vitamin B<sub>12</sub>--We are proposing to lower the RDI for Vitamin B<sub>12</sub> from 6 to 2.4 µg/day which reflects the population-coverage RDA for Vitamin B<sub>12</sub>. The RDAs for Vitamin B<sub>12</sub> were established by the IOM in 2000. The IOM noted that 10 to 30 percent of individuals older than 50 years of age are estimated to have atrophic gastritis with low stomach acid secretion which can decrease the bioavailability of naturally occurring vitamin B<sub>12</sub> in food (Ref. 17). The bioavailability of crystalline vitamin B<sub>12</sub> that is added to food is not altered in people with this condition. While the IOM set an RDA of 2.4 µg/d that can be met by consuming natural and crystalline forms of vitamin B<sub>12</sub> and is for all adults, it was noted that it is advisable that individuals older than 50 years of age meet their RDA mainly by consuming foods fortified with crystalline vitamin B<sub>12</sub> or vitamin B<sub>12</sub>-containing supplements. If the RDI is lowered from 6 to 2.4 µg, it is possible that the fortification level in foods, such as ready-to-eat breakfast cereals, may be lowered, decreasing the overall amount of crystalline vitamin B<sub>12</sub> in the food supply. Given the current level of fortification in food, less than 1 percent of men and 6.4 to 7.5 percent of women older than 50 years of age consume below the EAR for vitamin B<sub>12</sub>, while only 3 to 5 percent of men and women in this age group have serum vitamin B<sub>12</sub> levels that are considered to be inadequate (2003-2006 NHANES) (table 1). Reflecting the current food supply and

regulations, data from NHANES (2003-2006) indicate that ready-to-eat cereal is the primary source of crystalline B<sub>12</sub> added to food, providing approximately 14.6 percent of the total vitamin B<sub>12</sub> consumed by individuals 51 years of age and older (Ref. 139). Dietary supplements appear to be an important contributor of vitamin B<sub>12</sub> for this age group because the mean increase in vitamin B<sub>12</sub> intake ranged between 2.5 and 4.7 µg/d when comparing intake from food only compared to food plus dietary supplements (NHANES 2003-2006) (table 1). We request comment and data on lowering the RDI for vitamin B<sub>12</sub> to 2.4 µg.

Table 2.--Current and Proposed RDIs for Nutrition Labeling (Based on a 2,000 Calorie Intake for Adults and Children 4 or More Years of Age)

Nutrient	Current RDIs	Proposed RDIs
<u>Vitamins:</u>		
Biotin	300 micrograms	30 micrograms
Choline	550 <sup>1</sup> milligrams	550 milligrams
Folate	400 micrograms	400 micrograms DFE
Niacin	20 milligrams	16 milligrams NE
Pantothenic acid	10 milligrams	5 milligrams
Riboflavin	1.7 milligrams	1.3 milligrams
Thiamin	1.5 milligrams	1.2 milligrams
Vitamin A	5,000 International Units	900 micrograms RAE
Vitamin B <sub>6</sub>	2.0 milligrams	1.7 milligrams
Vitamin B <sub>12</sub>	6 micrograms	2.4 micrograms
Vitamin C	60 milligrams	90 milligrams
Vitamin D	400 International Units	20 micrograms
Vitamin E	30 International Units	15 milligrams
Vitamin K	80 micrograms	120 micrograms
<u>Minerals:</u>		
Calcium	1,000 milligrams	1,300 milligrams
Chloride	3,400 milligrams	2,300 milligrams
Chromium	120 micrograms	35 micrograms
Copper	2.0 milligrams	0.9 milligrams
Iodine	150 micrograms	150 micrograms
Iron	18 milligrams	18 milligrams
Magnesium	400 milligrams	420 milligrams
Manganese	2.0 milligrams	2.3 milligrams
Molybdenum	75 micrograms	45 micrograms
Phosphorus	1,000 milligrams	1,250 milligrams
Potassium <sup>2</sup>	3,500 milligrams	4,700 milligrams
Selenium	70 micrograms	55 micrograms
Zinc	15 milligrams	11 milligrams

RAE=Retinol activity equivalents; 1 RAE=1 mcg retinol, 12 mcg  $\beta$ -carotene, or 24 mcg  $\alpha$ -carotene, or 24 mcg  $\beta$ -cryptoxanthin.

NE=Niacin equivalents, 1 mg niacin=60 mg of tryptophan.

DFE=Dietary folate equivalents; 1 DFE=1 mcg food folate=0.6 mcg of folic acid from fortified food or as a supplement consumed with food.

<sup>1</sup>A notification was submitted under section 403(r)(2)(G) of the FD&C Act in 2001 for the use of certain nutrient content claims for choline. These statements identify the daily value for choline as 550 mg. This value is based on the AI set by the IOM of the NAS in 1998 (Refs. 138 and 137).

<sup>2</sup>These minerals currently have a DRV and we are proposing to establish an RDI.

## J. Units of Measure, Analytical Methods, and Terms for Vitamins and Minerals

As discussed in this document, the IOM set DRIs using new units of measure for vitamin A, vitamin E, and folate, as well as provided recommendations on the use of International Units (IUs), and expression of weight amounts for sodium, potassium, copper, and chloride (Refs. 17 to 19,25). The new units of measure for vitamin A, vitamin E, and folate affect how total amount of each nutrient is measured. The 2007 ANPRM asked several questions about these issues. We discuss our reconsideration of the units of measure, analytical methods, and terms used in declaration of specific vitamins and minerals in this section.

### 1. Sodium, Potassium, Copper, and Chloride

The absolute amount declaration for sodium, potassium, copper, and chloride must be expressed in mg (§ 101.9 (c)(8)(iv) and (c)(9)). However, in the DRI reports for these nutrients, these nutrients are expressed as grams (sodium, potassium, chloride) or micrograms (copper) (Refs. 21,140). The IOM Labeling Committee recommended that the current requirement for units of measurement used in the declaration of these nutrients should be changed to be consistent with the units used in the new DRI reports. In response to the 2007 ANPRM that asked about whether the units of measure should be changed for these nutrients, we received comments that generally supported maintaining the current units of measure.

We considered the IOM Labeling Committee recommendations and comments received. When expressed as "g" units, rather than in "mg" units, significant differences in the amounts of sodium or potassium could appear inconsequential or less significant. For example, amounts declared as 0.2 g and 0.5 g may not seem as significantly different as 200 mg and 500 mg. Furthermore, units of measure for these nutrients have been in use since 1993 and consumers may be already familiar with the units used on the label. In addition, the use of milligrams for

sodium and potassium is consistent with the 2010 DGA, which provides recommendations for sodium and potassium in milligram units (Ref. 6). We tentatively conclude that there is no advantage to change the units of measure for sodium, potassium, copper, or chloride from those currently in use. Thus, we are not proposing any changes to the units used for declaring these nutrients on the Nutrition Facts label.

## 2. Folate and Folic Acid

a. Units of Measure--The RDI for "folate" is listed in "micrograms" (§ 101.9 (c)(8)(iv)). Folate represents the sum of naturally occurring folate and synthetic folic acid that has been added to foods. In 1998, the IOM set the RDA for folate expressed as mcg Dietary Folate Equivalents (DFE) (Ref. 141). The IOM Labeling Committee recommended that the units used for folate (mcg) in nutrition labeling should be consistent with the units in the new DRI report (mcg DFE) (Ref. 25). In response to the 2007 ANPRM, in which we asked for comment on this issue, a few comments supported retaining the current units (mcg) for folate and one comment noted that the use of the term DFE on the label would be unfamiliar to consumers and could be confusing (Ref. 47). The IOM developed the new term, DFE, to account for the greater bioavailability of synthetic folic acid that is added to fortified foods or dietary supplements than folate that occurs naturally in foods (food folate). As defined by the IOM, mcg DFE is equivalent to mcg food folate +  $(1.7 \times \text{mcg synthetic folic acid})$  (Ref. 141). The current unit of measure (mcg) does not take into account the difference in the bioavailability of folate and folic acid. In addition, mcg DFE declaration would provide a more accurate representation of the amount of folate in foods that contain both naturally occurring folate and added folic acid. For example, the standards of identity for certain enriched foods require the addition of folic acid (21 CFR parts 136, 137, and 139) and, these foods contain both food folate and synthetic folic acid.

Therefore, we are proposing to amend § 101.9(c)(8)(iv) such that mcg DFE would be used to declare the amount of total folate (food folate and synthetic folic acid) on the Nutrition Facts label. Section 101.36(b)(2)(ii)(B) for the labeling of dietary supplements includes a reference to § 101.9(c)(8)(iv), which, as proposed, designates the units of measure for declaration of folic acid as mcg DFE units (see section II.L.).

We are aware that education efforts should be provided to assist with consumer understanding of the new "equivalent" units of measurement for folic acid. For example, using the new units, a dietary supplement that now declares 400 mcg of folic acid would declare the same amount as 680 mcg DFE or 170 percent of the proposed RDI. One option to help ensure consumer understanding would be to allow the declaration of the amount of folic acid in parenthesis similar to that permitted for the percent of vitamin A as  $\beta$ -carotene (§ 101.9(c)(8)(vi)). For example, for a conventional food that contains both folic acid and folate, the total mcg DFE could be declared and in parenthesis indicate how much is from folic acid. We invite comment on this approach.

b. Analytical Methods--Because we are proposing to amend the units used for declaring the sum of folate and folic acid, we considered the availability and limitations of analytical methods necessary to measure each nutrient separately for calculating mcg DFE. Available analytical methods (e.g., AOAC 960.46, 944.12, and 2004.05) cannot distinguish between naturally occurring folate in conventional food and folic acid that is added to conventional food products. There is a difference in folate activity between naturally occurring folate and synthetic folic acid that is added to fortify foods. When a conventional food product contains a mixture of naturally occurring folate and synthetic folic acid that has been added, available analytical methods do not allow for verification of the declared amount of mcg DFEs on the Nutrition Facts

label. To calculate DFEs, it is necessary to know both the amount of folate and folic acid in the food product. Therefore, proposed § 101.9(g)(10) would require manufacturers to make and keep records to verify the amount of folic acid added to the food and folate in the finished food, when a mixture of both naturally occurring folate and added folic acid are present in the food. (See section II.N.) We invite comment on available scientifically valid methods that are capable of measuring folic acid and folate separately.

c. Terms to Declare Folate--"Folic acid" or "folacin" are identified as synonyms of folate and can be added in parentheses after folate or can be listed without parentheses in lieu of "folate" on the Nutrition Facts label (§ 101.9 (c)(8)(v)) or in the Supplement Facts label (§ 101.36(b)(2)(B)(2)).

Consistent with the proposed amendments related to the units of measure for folate that take into account the differences between folate and folic acid, we are reconsidering appropriate terms for declaration of folate content in foods and dietary supplements. We are proposing to (1) eliminate the synonym "folacin" specified in §§ 101.9(c)(8)(v) and 101.36(b)(2)(B)(2); (2) require, in proposed § 101.9(c)(8)(vii), that the term "folate" be used in the labeling of conventional foods that contain either folate only or a mixture of folate and folic acid; and (3) require that the term "folic acid" be used in the labeling of dietary supplements only. As proposed, conventional foods would not be permitted to use the term "folic acid."

### 3. Vitamins A, D, and E

International Units (IUs) are used for the labeling of vitamins A, D, and E on the Nutrition and Supplements Facts labels (§§ 101.9(c)(8)(iv) and 101.36(b)(2)(ii)(B)). The IOM Labeling Committee recommended that the units for these nutrients should be changed to be consistent with the units in the new DRI reports, i.e., µg Retinol Activity Equivalents for vitamin

A,  $\mu\text{g}$  for vitamin D, and mg  $\alpha$ -tocopherol for vitamin E (Refs. 18,22,25,140). In response to the 2007 ANPRM, several comments supported replacing IUs with mcg RAE for vitamin A,  $\mu\text{g}$  for vitamin D, and mg  $\alpha$ -tocopherol for vitamin E. We agree that IUs should be replaced with units that are consistent with the DRIs. In addition, because DRIs form the basis for the proposed RDIs for these vitamins (see section II.I.), using the new units would also correspond with the proposed RDIs for vitamins A, D, and E. We discuss issues relevant to vitamin A and vitamin E units of activity in this document.

a. Units of Vitamin A Activity--The RDI for vitamin A is 5,000 IU (§ 101.9(c)(8)(iv)). Because the vitamin A activity of provitamin A carotenoids (e.g.,  $\beta$ -carotene) is less than pre-formed vitamin A (retinol), the following conversions were developed: One mcg retinol = 3.33 IU vitamin A activity from retinol (Ref. 105) and 10 IU  $\beta$ -carotene = 3.33 IU retinol (Ref. 105). Because the vitamin A activity of  $\beta$ -carotene in dietary supplements is greater than  $\beta$ -carotene in food, ten IU of  $\beta$ -carotene is based on 3.33 IU of vitamin A activity  $\times$  3 (the relative vitamin A activity of  $\beta$ -carotene in supplements versus diets). The RDA in mcg Retinol Equivalents (RE) for vitamin A is equivalent to 1 mcg retinol or 6 mcg of  $\beta$ -carotene (i.e., carotene:retinol equivalency ratio of 6:1) and considers 3 mcg of dietary  $\beta$ -carotene to be equivalent to 1 mcg of purified  $\beta$ -carotene in supplements (i.e., a carotene:retinol equivalency ratio of 3:1).

A comment to the 2007 ANPRM noted that the IU for vitamin A does not take into account the recent information on the bioavailability of dietary provitamin A carotenoids that was used to define retinol activity equivalents (RAEs) for these carotenoids (Ref. 105). The unit of measure associated with the RDA for vitamin A is mcg RE. We agree that the IU for vitamin A does not reflect the carotene:retinol equivalency ratio. RAEs consider 6 mcg of dietary  $\beta$ -carotene to be equivalent to 1 mcg of purified  $\beta$ -carotene in supplements (i.e., a carotene:retinol

equivalency ratio of 6:1) because more recent evidence suggests that the bioavailability of  $\beta$ -carotene is approximately half of what was previously considered for setting mcg RE. A change in units does not present any challenges to AOAC methods used for measuring provitamin A carotenoids and vitamin A in foods or dietary supplements.

Therefore, proposed § 101.9(c)(8)(iv) would change the units of measure for vitamin A to replace "IU" with "mcg," representing mcg RAE. In addition, because the difference in the bioconversion of  $\beta$ -carotene to vitamin A will be accounted for with the proposed declaration of vitamin A content as "mcg" (representing mcg RAE), we are not proposing to preclude the declaration of  $\beta$ -carotene in conventional foods as vitamin A. A corresponding change for dietary supplements is made in proposed § 101.36(b)(2)(i)(B)(3).

b. Units of Vitamin E Activity--The RDI for vitamin E is 30 IU (§ 101.9(c)(8)(iv)). Before 1980, one IU of vitamin E activity was defined as 1 mg of dl- $\alpha$ -tocopherol acetate by the U. S. Pharmacopeia (USP) (Ref. 142). After 1980, the IU was changed to the USP unit where one USP unit of vitamin E was still defined as having 1 mg of all rac- $\alpha$ -tocopherol acetate. Therefore there is no longer an IU for vitamin E (Ref. 142). One comment to the 2007 ANPRM said that the current RDI of 30 IU underestimates the amount of vitamin E naturally present in foods. We agree. The RDA for vitamin E is 15 mg/d of  $\alpha$ -tocopherol (Ref. 143).  $\alpha$ -Tocopherol is the only form of vitamin E that is maintained in blood and has biological activity. There are eight stereoisomers of  $\alpha$ -tocopherol (RRR, RSR, RRS, RSS, SRR, SSR, SRS, SSS). Of the eight, only RRR  $\alpha$ -tocopherol occurs naturally in foods. Commercially available vitamin E that is used to fortify foods and used in dietary supplements contains esters of either the natural RRR- or, more commonly, mixtures of the 8 stereoisomers (all rac  $\alpha$ -tocopherol acetate). Four of the eight stereoisomers of  $\alpha$ -tocopherol are not maintained in human plasma or tissues (SRR, SSR,

SRS, and SSS). Thus, the new RDA for vitamin E is limited to the four 2R stereoisomeric forms (RRR, RSR, RRS and RSS) of  $\alpha$ -tocopherol (Ref. 143). These four forms of  $\alpha$ -tocopherol are found in nonfortified and fortified conventional foods and dietary supplements. The all rac- $\alpha$ -tocopherol acetate in fortified foods or dietary supplements has one-half the activity of RRR- $\alpha$ -tocopherol naturally found in foods or the 2R stereoisomeric forms of  $\alpha$ -tocopherol. Unlike the IU, the new IOM measure of vitamin E activity, mg  $\alpha$ -tocopherol accounts for this difference in activity between naturally occurring and synthetic vitamin E. Therefore, proposed § 101.9(c)(8)(iv) would change the units of measure for vitamin E to replace "IU" with "mg," representing mg of  $\alpha$ -tocopherol. Section 101.36(b)(2)(ii)(B) for the labeling of dietary supplements includes a reference to § 101.9(c)(8)(iv), which, as proposed, designates the units of measure for declaration of vitamin E as "mg."

Because of the difference in vitamin E activity between all rac- $\alpha$ -tocopherol acetate and RRR- $\alpha$ -tocopherol, AOAC methods or other validated analytical methods would be needed for individually measuring naturally occurring vitamin E (RRR- $\alpha$ -tocopherol) and all rac- $\alpha$ -tocopherol acetate in food products. Current AOAC methods cannot individually measure these two forms of vitamin E. In addition, it is necessary to know the amount of both RRR- $\alpha$ -tocopherol and all rac- $\alpha$ -tocopherol acetate in a food product to calculate vitamin E equivalents for declaration as mg  $\alpha$ -tocopherol. It is not possible to determine the amount of RRR- $\alpha$ -tocopherol in a food product by subtracting the amount of all rac- $\alpha$ -tocopherol acetate from the total amount of vitamin E declared. Therefore, when a conventional food contains a mixture of all rac- $\alpha$ -tocopherol acetate and RRR- $\alpha$ -tocopherol, we are proposing to require manufacturers to verify the declared amount of both all rac- $\alpha$ -tocopherol acetate and RRR- $\alpha$ -tocopherol in the finished food product (proposed § 101.9(g)(10)). (See section II.N.) We invite comment on

available validated methods that are capable of individually measuring all rac- $\alpha$ -tocopherol acetate and RRR- $\alpha$ -tocopherol.

For the reasons stated previously, we are proposing to amend § 101.9(c)(8)(iv) to replace IUs for the RDIs for vitamin A, vitamin D, and vitamin E with mcg RAE for vitamin A,  $\mu$ g for vitamin D, and mg  $\alpha$ -tocopherol for vitamin E.

#### K. Labeling of Foods for Infants, Young Children, and Pregnant or Lactating Women

The general labeling requirements for foods in § 101.9(c) apply to foods for infants, young children, and pregnant and lactating women with certain exceptions. For example, foods, other than infant formula, represented or purported to be specifically for infants and children less than 4 years of age are not permitted to include declarations of percent DV for the following nutrients: Total fat, saturated fat, cholesterol, sodium, potassium, total carbohydrate and dietary fiber (§ 101.9(j)(5)(ii)(A)). There are additional exceptions to labeling for foods, other than infant formula, represented or purported to be specifically for infants and children less than 2 years of age. For example, these foods are also not permitted to declare calories from fat, calories from saturated fat, saturated fat, polyunsaturated fat, monounsaturated fat and cholesterol on the Nutrition Facts label (§ 101.9(j)(5)(i)).

FDA regulations do not include DRVs or RDIs for nutrients, generally, for infants, children under 4 years of age, or pregnant and lactating women. However, there are requirements for a DRV for protein for children 4 or more years of age, and an RDI for protein for each of the following subpopulations: (1) Children less than 4 years of age; 2) infants; 3) pregnant women; and 4) lactating women (§ 101.9(c)(7)(iii)). In the preamble to the 1993 DRV/RDI final rule, we included a table listing RDIs for various nutrients for these subpopulations, based on the 1968 NAS RDAs (58 FR 2206 at 2213). These RDIs also appear in

FDA's Food Labeling Guide (Ref. 144) and we are aware that some manufacturers use these RDIs in labeling foods represented or purported to be specifically for these subpopulations.

We are reconsidering the requirements for the labeling of foods, other than infant formula, represented or purported to be specifically for infants, children under 4 years of age, and pregnant and lactating women, in light of current recommendations in consensus reports and proposed changes to the Nutrition Facts label discussed in sections II.A. to II.J., and comments to the 2007 ANPRM. We are proposing various changes, which we discuss in this document.

#### 1. Age Range for Infants and Young Children

FDA regulations use the age ranges "less than 2 years of age" and "less than 4 years of age" to establish labeling requirements for foods represented or purported to be specifically for infants and young children (§ 101.9(j)(5)). The 2007 ANPRM did not ask for comments on this issue, but several comments (Ref. 47) recommended that we change the current age categories to infants 7 to 12 months and young children 1 through 3 years (13 through 48 months), consistent with the age ranges used in the IOM's age-specific DRI recommendations.

In general, we consider it appropriate to adopt the same age categories as those used in the IOM DRIs for infants and children because our proposed DVs are based on these age-specific DRIs. With respect to the infant category, the nutritional requirements of infants 0 to 6 months should be met almost exclusively by breast milk or infant formula (Refs. 145 and 146). Therefore, regulations for the labeling of foods, other than infant formula, represented or purported to be specifically for infants 0 to 6 months of age are not necessary or appropriate. However, infants are transitioning to eating solid foods by 7 through 12 months. There are a number of foods in the marketplace identified for this age group. Therefore, we are proposing a

separate category of foods represented or purported to be specifically for infants 7 through 12 months.

With respect to children 1 through 3 years of age, using the DRI age range would result in infants no longer being the lower end of the age range in the category of infants and children less than 2 years and less than 4 years of age as specified in § 101.9(j)(5). Young children who are 1 year of age would be the lower end of the age range. Assigning DVs for children 1 through 3 years of age would ensure consistency with the 1 through 3 year toddler age category established for RACCs specified in § 101.12(a)(2). Moreover, because the growth velocity in height is most similar for children 1 through 3 years of age, we consider it appropriate to revise the age range to include children of these ages into a single category for food labeling purposes (Ref. 15).

Therefore, we are proposing to revise the exceptions for requirements for nutrition labeling provided in § 101.9(j)(5)(i) and the exception to the requirement for the format used for nutrient information on food labeling in § 101.9(d)(1) for foods represented or purported to be specifically for infants and children less than 4 years of age. Specifically, we are proposing to replace the current category of infants and children less than 4 years with infants 7 through 12 months and children 1 through 3 years of age.

## 2. Mandatory Declaration of Calories and Statutorily Required Nutrients

Currently, foods, other than infant formula, represented or purported to be specifically for infants and children less than 4 years must declare statutorily required nutrients, including calories, calories from fat, total fat, saturated fat, cholesterol, sodium, total carbohydrate, sugars, dietary fiber, and protein. For foods, other than infant formula, represented or purported to be for infants and children less than 2 years, the declaration of certain statutorily required nutrients,

which include calories from fat, saturated fat, and cholesterol, is not required or permitted (§ 101.9(j)(5)(i)).

a. Declaration of Saturated Fat and Cholesterol--One comment to the 2007 ANPRM noted that the diet of U. S. infants is nutritionally adequate with negligible risk of nutrient deficiency and recommended continuing to require the declaration of calories and the amount of total fat, total carbohydrate, dietary fiber, sugars, and total protein on the Nutrition Facts label of foods for infants. Another comment supported mandatory declaration of saturated fat on food products for children less than 2 years of age.

As discussed in section II.K.1., we are proposing new categories of infants 7 through 12 months and children 1 through 3 years of age. We are considering, in this proposed rule, whether there is a need to require or permit the declaration of calories from fat, saturated fat, and cholesterol in the labeling for foods represented or purported to be specifically for these subpopulations. In section II.A.1., we discuss our intent to revise § 101.9(c)(1)(ii) to no longer require and not permit the declaration of calories from fat on the Nutrition Fact label. Therefore, if these proposed changes are finalized, the exceptions in § 101.9(j)(5)(i) would no longer be needed.

With respect to saturated fat and cholesterol, we did not require or permit the labeling of any fat or fatty acid on foods represented or purported to be specifically for children less than 2 years because consensus reports noted the need for the higher percentage of calories from fat for this subpopulation and that nutrient guidelines on fats, cholesterol and calories for children less than 2 years of age is inappropriate (58 FR 2079 at 2150). A recent consensus report continues to recommend that fat intake in infants less than 12 months of age should not be restricted; however, there is no discussion or recommendation about not providing nutrient guidelines for

fat and cholesterol to children under the age of 2 years (Ref. 146). While fat is still considered to be an important source of calories for infants and young children, recent evidence suggests that a diet with saturated fat less than 10 percent of calories and cholesterol intake less than 300 mg/d can safely and effectively reduce the levels of total and LDL cholesterol in healthy children (Ref. 146). This type of diet may have similar effects when started in infancy and sustained throughout childhood into adolescence (Ref. 146). Furthermore, the 2010 DGA recommended that Americans 2 years of age and older consume less saturated fatty acids and less than 300 mg/d of cholesterol (Ref. 6).

We tentatively conclude that, except for the declaration of calories from fat, the declaration of statutorily required nutrients that include saturated fat and cholesterol on the label of foods represented or purported to be specifically for infants 7 through 12 months and children 1 through 3 years of age should be mandatory because: (1) The declaration of calories and these nutrients is mandated by section 403(q) of the FD&C Act and we have no basis on which to not require or permit their declaration as discussed previously; and (2) these nutrients are essential in fostering growth and maintaining good health during a critical stage of human development and physiology (Ref. 147 p. 71) and, therefore, their mandatory declaration can assist in maintaining healthy dietary practices. Therefore, we are proposing to remove current § 101.9(j)(5)(i) and revise and re-designate current § 101.9(j)(5)(ii) as § 101.9(j)(5)(i).

We request comment on our tentative conclusions and any available relevant empirical research as to whether the proposed declaration of saturated fat and cholesterol for these subpopulations is likely to be confusing to consumers or otherwise result in restriction of fat intakes among infants 7 through 12 months or children 1 through 3 years of age.

Currently, foods consumed by pregnant and lactating women must declare statutorily required nutrients, including calories, calories from fat, total fat, saturated fat, cholesterol, sodium, total carbohydrate, sugars, dietary fiber, and protein. Women of reproductive age consume the same foods as the general population and, in general, continue consuming similar foods during pregnancy and lactation. We tentatively conclude that, except for the declaration of calories from fat, the declaration of statutorily required nutrients should be mandatory because the declaration of calories and these nutrients is mandated by section 403(q) of the FD&C Act and we have no basis on which to not require or permit their declaration as discussed previously.

Accordingly, we are proposing to require the mandatory declaration of calories, and the amount of total fat, saturated fat, trans fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, and protein on foods represented or purported to be specifically for infants 7 through 12 months of age, children 1 through 3 years of age, and pregnant and lactating women, and permit the declaration of calories from saturated fat such that these nutrients would be subject to the same requirements applicable to foods for the general population.

A comment to the 2007 ANPRM requested that we permit the use of a footnote statement about not limiting fat intake on foods represented or purported to be specifically for infants and children less than 2 years to enable consumers to make informed choices, should the Agency decide to propose the mandatory declaration of saturated fat for infants and children less than 2 years. The comment noted that saturated fat should not be limited in the diets of children less than 2 years of age. The comment provided no consumer data about such a footnote statement. At this time, we are not proposing to require a footnote stating that total fat and other types of fat should not be limited in infants and children less than 2 years in response to this comment. However, we request comments and information on how consumers would understand and use

the amount of saturated fat and cholesterol declared on the Nutrition Facts label, as well as on the need for an explanatory footnote to accompany the declaration of saturated fat and cholesterol, on foods represented or purported to be specifically for infants 7 through 12 months or children 1 through 3 years.

b. Percent DV Declaration--Currently, the percent DV declaration is not permitted on the food label for foods, other than infant formula, represented or purported to be specifically for infants and children less than 4 years (which includes infants and children less than 2 years) for total fat, saturated fat, cholesterol, sodium, potassium, total carbohydrate, and dietary fiber (§ 101.9(j)(5)(ii)). Percent DV is required for protein and vitamins and other minerals. We tentatively conclude that it is appropriate to require declarations of percent DV for those nutrients for which we are establishing a DRV or RDI for infants 7 to 12 months, for children 1 through 3 years of age, and for pregnant and lactating women (see the discussion in this document for the nutrients in each subpopulation for which FDA is establishing a DRV or RDI). This change is reflected in re-designated § 101.9(j)(5)(i). The percent DV, as discussed in section II.B.3., provides information in a manner which enables consumers to understand the relative significance of nutrition information in the context of a total daily diet.

One comment to the 2007 ANPRM suggested that the percent DV declaration for protein should be voluntary for all infant products, unless a claim is made for protein because protein intake and quality appear to be adequate for infants (Refs. 148 and 149). As we previously stated, protein is of critical importance in maintaining good health because it supplies essential amino acids and is a principal source of calories along with fat and carbohydrate (55 FR 29487 at 29499). Current evidence suggests that protein intake is adequate in infants and young children and the majority of protein sources in their diets constitute high quality protein sources (Ref.

150). However, the level and quality of protein present in a food remain an important consideration in food selection for infants because infant diets are derived from a limited number of foods (55 FR 29487 at 29499). For example, at 6 to 11 months of age, approximately 46 percent of the total protein intake comes from sources other than breast milk, formula, and cow's milk (e.g., baby foods and meats) (Ref. 149). The percentage increases at ages 12 to 24 months to 63 percent (Ref. 149). Calculating the percent DV for protein incorporates a measure of protein quality (e.g., a corrected protein amount obtained from the protein digestibility-corrected amino acid score) (§ 101.9 (c)(7)(i)). Thus, the percent DV declaration is a useful tool to indicate protein quality to the consumer. As such, we disagree that the percent DV declaration for protein should be voluntary. Because of the importance of adequate high quality protein in the diets of infants and young children, we tentatively conclude that the percent DV declaration for protein is necessary to assist consumers in maintaining healthy dietary practices among infants and young children 1 through 3 years of age.

### 3. Declaration of Non-Statutory Nutrients Other Than Essential Vitamins and Minerals

Foods, other than infant formula, represented or purported to be specifically for infants and children less than 2 years of age are not permitted to declare calories from saturated fat and the amount of polyunsaturated fat and monounsaturated fat (§ 101.9(j)(5)(i)), whereas soluble fiber, insoluble fiber, and sugar alcohols can be voluntarily declared. Polyunsaturated fat, monounsaturated fat, soluble fiber, insoluble fiber, and sugar alcohols can be voluntarily declared on the label of foods represented or purported to be specifically for children 2 through 4 years of age, and pregnant and lactating women.

Section I.C. includes a discussion of the factors that we consider in proposing the requirements for declaration of non-statutorily required nutrients on the Nutrition Facts label of

foods (e.g., polyunsaturated fat, monounsaturated fat, soluble fiber, insoluble fiber, and sugar alcohols). These factors include the availability of information from consensus reports, including evidence for the public health significance of a nutrient. Consensus reports that provide information about the relationship between nutrients and chronic diseases, health-related conditions, or health-related physiological endpoints are generally not available for infants 7 to 12 months. Therefore, for foods represented or purported to be for these infants, we are not considering consensus reports in the way described in section I.C., but, rather, we are considering other types of information that are available from consensus reports applicable to this subpopulation. With respect to certain nutrition declaration requirements, we determined there was not sufficient evidence to propose a change to the regulations. In addition, we determined that, in some cases, there is not sufficient evidence to propose different requirements for foods represented or purported to be specifically for infants 7 through 12 months than for foods represented or purported to be specifically for children 1 through 3 years of age.

For foods represented or purported to be specifically for children 1 through 3 years of age and pregnant and lactating women, we considered the factors in section I.C. to determine whether to propose the mandatory or voluntary declaration of non-statutory nutrients. Most advisory consensus and policy reports on which we rely for the general population apply to children 2 years of age and older and pregnant and lactating women, unless noted otherwise (e.g., 2010 DGAC and health claims (§ 101.14(e)(5))). While the recommendations in these reports are for 2 years of age and older, we are using the information in these consensus reports for considering the factors in section I.C. for children 1 through 3 years of age because it is not expected that the role of these nutrients in health would be markedly different between 1 and 2 year olds. Moreover, the IOM has established the DRI ranges for 1 to 3 year olds.

a. Voluntary Declaration of Calories From Saturated Fat, and the Amount of Polyunsaturated and Monounsaturated Fat--For infants 7 to 12 months, there are no specific recommendations provided about calories from saturated or polyunsaturated or monounsaturated fat. However, as discussed previously, there is some evidence to suggest that reduction of total and LDL cholesterol levels can occur with reducing saturated fat intake to less than 10 percent of calories, beginning in infancy and sustained throughout childhood into adolescence (Ref. 146). Furthermore, consensus reports provide no discussion or recommendation about not providing nutrient guidelines for fatty acids to children under the age of 2 years and there is no evidence to suggest that infants 7 through 12 months of age would be different than children 1 through 3 years of age. Therefore, we tentatively conclude that there is no basis to continue to provide an exception that does not permit the declaration of calories from saturated fat, or polyunsaturated and monounsaturated fats on foods represented or purported to be specifically for infants and children less than 2 years of age.

Quantitative intake recommendations are not available from relevant U. S. consensus reports for monounsaturated and polyunsaturated fats for children 1 through 3 years of age or pregnant and lactating women. There is well-established evidence to indicate that replacing saturated fatty acids with polyunsaturated and monounsaturated fatty acids reduces blood LDL cholesterol levels and, therefore, the risk of CVD (Ref. 6). Because monounsaturated and polyunsaturated fats have public health significance when they replace saturated fat, consistent with the factors we consider for voluntary declaration discussed in section I.C., we tentatively conclude that not permitting the declaration of polyunsaturated and monounsaturated fat on foods represented or purported to be specifically for children less than 2 years of age in § 101.9(j)(5)(i) is no longer necessary.

Therefore, we are proposing to revise § 101.9(j)(5)(i) to remove the exceptions for the declaration of calories from saturated fat, and the amount of polyunsaturated fat and monounsaturated fat on foods represented or purported to be specifically for children less than 2 years of age. If finalized, these declarations would be the same as the proposed voluntary declarations for foods for the general population (see sections II.A.2, II.B.4, and II.B.5., respectively).

b. Voluntary Declaration of Soluble Fiber, Insoluble Fiber, and Sugar Alcohols--As discussed in section II.D., while quantitative intake recommendations are lacking for soluble fiber, insoluble fiber, and sugar alcohols, there is well established evidence for the role of these nutrients in chronic disease risk, risk of a health-related or a physiological endpoint (i.e., CHD, laxation or dental caries) (Ref. 66 and §§ 101.76, 101.77, 101.80, and 101.81). There is no evidence to suggest that the role of these nutrients would be different among infants 7 through 12 months, children 1 through 3 years of age, or pregnant and lactating women compared to the general population.

Accordingly, we are not proposing any changes to the provisions for the voluntary declaration of soluble fiber, insoluble fiber, and sugar alcohols on the label of foods represented or purported to be specifically for infants 7 to 12 months, children 1 through 3 years of age, or pregnant and lactating women.

c. Mandatory Declaration of Trans Fat--Trans fat is required to be declared on the Nutrition Facts label and regulations do not provide exceptions for foods represented or purported to be specifically for infants, young children, or pregnant and lactating women. One comment to the 2007 ANPRM recommended eliminating mandatory trans fat labeling when total fat is declared as 0 g in the Nutrition Facts label of foods for infants.

As explained in section II.B.3., we are not proposing any changes to the mandatory declaration of trans fat in the labeling of foods intended for the general population. The relationship between the consumption of trans fat and risk of CHD is well established (Refs. 6 and 49). Cardiovascular disease is also known to begin in childhood (Refs. 146 and 151). Thus, we tentatively conclude that declaration of trans fat continues to be necessary to assist consumers in maintaining health dietary practices, including among infants, young children, and pregnant and lactating women.

Trans fat declaration is voluntary when the total fat content of a food is less than 0.5 g (§ 101.9(c)(2)(ii)). In addition, if a manufacturer does not declare the trans fat content because total fat amount is less than 0.5 g, then the statement "Not a significant source of trans fat" must be placed at the bottom of the table of nutrient values. This statement indicates why information that is required to be declared is omitted and provides necessary information to assist in making healthy dietary choices (55 FR 29487 at 29502). The statement is also helpful in minimizing space requirements for labels that do not meet the simplified label format requirements (58 FR 2079 at 2084).

Therefore, we are not proposing any changes to the mandatory declaration of trans fat on the label of foods represented or purported to be specifically for infants, children 1 through 3 years of age, or pregnant and lactating women.

d. Mandatory Declaration of Added Sugars--Whereas FDA regulations do not provide for the declaration of added sugars on the Nutrition Facts label, as explained in section II.D.3., we are proposing to require the mandatory declaration of added sugars on the Nutrition Facts label. The 2010 DGA provides recommendations for consumption of added sugars for the U. S. population 2 years of age and older, but not for infants and children under age two. However,

we would not expect the recommendations for added sugars for a 2 year old to be different from that of a 1 year old because we do not expect the role of added sugars in health to be markedly different between children 1 and 2 year olds. Moreover, the IOM has established DRI ranges for 1 through 3 year olds because growth velocity is most similar during this age range (Ref. 15). Further, mandatory declaration of added sugars would be important for foods for infants 7 through 12 months, as it is for the general population, to assist consumers in choosing nutrient-dense foods for infants 7 through 12 months during this phase of accelerated growth and development. Moreover, we do not have any information that providing added sugars information on the Nutrition Facts label of foods marketed to the subpopulations of infants 7 through 12 months and children 1 to 3 years of age would not assist in maintaining healthy dietary practices.

Therefore, we are proposing the mandatory declaration of added sugars on the Nutrition Facts label of foods represented or purported to be specifically for infants 7 through 12 months, children 1 through 3 years of age, and pregnant and lactating women. We request comment on our tentative conclusion.

e. Voluntary Declaration of Fluoride--FDA regulations do not provide for the declaration of fluoride on the Nutrition Facts label of any foods. For the reasons discussed in section II.G., we are proposing to permit voluntary declaration of fluoride on the labeling of foods for the general population based on the factors we consider in section I.C. and fluoride's role in reducing the risk of dental caries. Because fluoride provides protection against dental caries by strengthening the tooth enamel before and after teeth appear (Ref. 90) and because excessive fluoride intake can cause dental fluorosis in young children (Ref. 92), we tentatively conclude that the declaration of fluoride on foods represented or purported to be specifically for children 1

through 3 years of age, and pregnant and lactating women can assist in maintaining healthy dietary practices. While evidence on dental caries is lacking for infants 7 through 12 months of age, there is no reason to expect the role of fluoride in the protection against dental caries to be different from other age groups. Therefore, proposed § 101.9(c)(5) would permit the voluntary declaration of fluoride on foods represented or purported to be specifically for infants 7 through 12 months of age, children 1 through 3 years of age, and pregnant and lactating women.

#### 4. Declaration of Essential Vitamins and Minerals

The declarations of vitamin A, vitamin C, calcium, and iron are required on the Nutrition Facts label, and there are no specific exceptions to this requirement for foods represented or purported to be specifically for infants and children less than 2 years and children less than 4 years of age, and pregnant and lactating women. We considered the factors for mandatory and voluntary declaration of nutrients discussed in section I.C., as applicable, to determine whether to propose to require or permit certain vitamins and minerals in the labeling of foods for infants, children, and pregnant and lactating women.

The AIs for essential vitamins and minerals (and RDAs for iron and zinc) for infants 7 to 12 months of age are based on the average intake of nutrients that infants consumed from breast milk, complementary foods, and/or supplements with the understanding that these sources provided sufficient amounts of the nutrients to meet the infant's daily needs (Refs. 18, 22, and 23). Therefore, the AIs (as well as the RDAs for iron and zinc) for infants were not based on endpoints related to chronic disease risk, or a health-related conditions or health-related physiology. Furthermore, because the AI represents intakes that are considered adequate and are based on average nutrient intakes from breast milk, foods, and/or supplements, the presence of an AI indicates that there is not a public health concern about adequate intake of that nutrient.

Therefore, we could not determine public health significance for a nutrient during infancy based on an AI for infants. Instead, we considered the importance of the nutrient in establishing healthy dietary practices during infancy for later in life, as well as the relevant available information for children 1 through 3 months of age that may also be applicable to infants. For nutrients with an RDA for infants 7 through 12 months of age (i.e., iron and zinc), we considered the factors for mandatory and voluntary labeling described in section I.C. to determine whether to propose mandatory or voluntary labeling for the nutrient.

For the declaration of essential vitamins and minerals for children 1 through 3 years of age and pregnant and lactating women, we propose the same considerations based on the same rationale as we set forth and proposed for the general population because scientific and policy considerations are generally the same and the DGA recommendations apply to Americans 2 years of age and older. While NHANES data were collected in lactating women, these data are not included in our analysis in this document because the sample size of lactating women was small and, thus, we could not reliably estimate mean intake and status of this population. However, the conclusions made about nutrient inadequacy during pregnancy are applied to lactating women since the needs of essential vitamin and minerals are increased for both pregnant and lactating women. Therefore, we are proposing the requirements related to essential vitamins and minerals in the labeling of foods for pregnant women and those for foods for lactating women should be the same. Accordingly, we are proposing to remove the provision in § 101.9(c)(8)(i) that requires separate declaration of percent DVs based on both RDI values for pregnant women and for lactating women in the labeling of foods represented or purported to be for use by both pregnant and lactating women.

We did not ask questions related to this issue in the 2007 ANPRM, but received some comments which we considered in reaching our tentative conclusions discussed in this document.

a. Mandatory Declaration of Calcium and Iron--We are not proposing any changes to the mandatory declaration of calcium on foods for the general population (see section II.H.1.). The AI for calcium for infants 7 through 12 months of age is based on average calcium consumption of these nutrients, rather than chronic disease risk, health related-condition, or physiological endpoints (Ref. 152). For children 1 through 3 years of age, and pregnant and lactating women, the RDAs for calcium are based, in part, on bone health (Ref. 22). One comment to the 2007 ANPRM recommended mandatory declaration of calcium and iron for labeling of foods for young children.

Our analysis of NHANES 2003-2006 data estimated that infants ages 7 to 12 months have usual calcium intakes above the AI (table 3). Our analysis of NHANES 2003-2006 estimated that about 12 percent of children 1 through 3 years of age had usual intakes of calcium below the EAR, based on intakes from conventional foods only (table 4). The percentage did not change when supplements were included. We are unable to consider biomarker data because sensitive biochemical indicators reflecting calcium nutritional status are lacking. Promoting the development of eating patterns that are associated with adequate calcium intake later in life is important (Ref. 153) given that calcium intakes are inadequate for the majority of the population (see table 1). Intakes of calcium, which is necessary for growth and bone development, are inadequate among children. Similar to the general population, approximately 20 percent of pregnant women consumed less than the EAR for calcium from conventional foods as well as from conventional foods and supplements (table 5).

Consistent with the factors we consider for essential vitamins and minerals (see section I.C.), we tentatively conclude that calcium is a nutrient of public health significance for children 1 through 3 years of age, and pregnant and lactating women. Because calcium is important for growth and development, we tentatively conclude that calcium is of public health significance for infants 7 through 12 months of age. As such, we agree with the comment that recommended mandatory declaration of calcium for foods purported to be specifically for young children.

We are not proposing any changes to the mandatory declaration of iron on foods for the general population (see section II.H.1.). Although the EAR and RDA are based on daily iron requirements and not directly on chronic disease risk, iron deficiency is associated with delayed normal infant motor function (i.e., normal activity and movement) and mental function (i.e., normal thinking and processing skills) (Ref. 100). Our analysis of NHANES 2003-2006 data estimated that about 18 percent of infants ages 7 to 12 months have usual iron intakes below the EAR, based on intakes from conventional foods only and 4 percent of infants ages 7 to 12 months have usual iron intakes below the EAR based on intakes from conventional foods and supplements (table 3).

For children 1 through 3 years of age, about 1 percent of children have usual iron intakes below the EAR, based on intakes from conventional foods only and 0.4 percent of children have usual iron intakes below the EAR based on intakes from conventional foods and supplements (table 4). The IOM set the EAR by modeling components of iron requirements. While total iron intakes appear adequate, the prevalence of iron deficiency in children ages 1 to 2 years has been reported to be 14.4 percent and the prevalence of iron deficiency anemia in children younger than 5 years has been reported to be 14.9 percent (Refs. 74 and 154). Therefore, we agree with

the comment that recommended mandatory declaration of iron in the labeling of foods for young children.

Inadequate iron intakes during pregnancy are also of public health significance because of the adverse effects for both the mother and the fetus (such as maternal anemia, premature delivery, low birth weight, and increased perinatal infant mortality) (Ref. 15). Our analysis of data collected by NHANES 2003-2006 estimated that 5 percent of pregnant women 14 to 50 years of age had usual iron intakes below the EAR based on intakes from conventional foods and 4 percent of pregnant women 14 to 50 years of age had usual iron intakes below the EAR based on intakes from conventional foods and supplements (table 5). The EAR for iron for pregnant women was based on estimates of iron stores needed during the first trimester (Ref. 100). Our analysis of 2003-2006 NHANES data indicate that among pregnant women aged 12 to 49 years, 25 percent were iron deficient and 13 percent had iron deficiency anemia. For the purpose of this analysis, iron deficiency was based on two out of three cutoffs of iron deficiency variables (transferrin saturation, serum ferritin, and erythrocyte protoporphyrin) (Ref. 155). While intakes appear adequate for most individuals, the prevalence of iron deficiency and iron deficiency anemia indicates that iron deficiency is of public health significance for pregnant women. As discussed in section II.H.1., iron is of public health significance for women of childbearing age. Therefore, we tentatively conclude that iron is a nutrient of public health significance for lactating women as well.

Because calcium and iron have quantitative intake recommendations and are considered to have public health significance for infants 7 through 12 months, children 1 through 3 years of age, and pregnant and lactating women, we tentatively conclude that the declaration of calcium and iron is necessary to assist consumers in maintaining healthy dietary practices. Accordingly,

proposed § 101.9(c)(8)(ii) would require the mandatory declaration of calcium and iron on foods represented or purported to be specifically for infants 7 to 12 months, children 1 through 3 years of age, or pregnant and lactating women; we are not providing for any exceptions for these subpopulations from the requirement for declaration of calcium and iron applicable to foods for the general population.

b. Mandatory Declaration of Vitamin D and Potassium--We are proposing to require the declaration of vitamin D on foods for the general population (see section II.H.1.). The AI for vitamin D for infants was based on maintenance of serum 25(OH)D concentrations at a level to achieve and maintain serum 25(OH)D concentrations above a defined level (30 to 50 nmol/L) in order to meet the needs of the majority of the infants and support bone accretion (Ref. 22). DRIs (EAR and RDA) for vitamin D were established at a level to achieve and maintain serum 25(OH)D concentrations above a defined level (40 to 50 nmol/L) in order to maintain bone health for children 1 through 3 years of age and pregnant women (Ref. 22).

Serum 25(OH)D data were not available in NHANES 2003-2006 for infants ages 7 to 12 months. Our analysis of NHANES 2003-2006 dietary data shows that 28.7 and 33.6 percent of infants ages 7 to 12 months have usual vitamin D intakes above the AI from conventional foods and conventional foods plus supplements, respectively (table 3).

Our analysis of NHANES 2003-2006 data shows that about 3 percent of children 1 through 3 years of age had serum 25(OH)D levels below 40 nmol/L (a level set by IOM as equivalent to EAR, see section II.H.2.a). Analysis of NHANES 2005-2008 dietary data shows that, assuming minimal sun exposure, about 82 percent of these children had usual vitamin D intakes below the EAR from conventional foods only and 66 percent had usual intakes below the EAR from conventional foods and supplements (table 4). For pregnant women, 15 percent had

serum 25(OH)D levels below 40 nmol/L, while about 88 percent of pregnant women had usual vitamin D intakes below the EAR from conventional foods only and 48 percent had usual intakes below the EAR from conventional foods and supplements (table 5). In addition to data on vitamin D status and intake, we considered other scientific and policy considerations, such as the importance of the nutrient in establishing healthy dietary practices for later life for children 1 through 3 years of age and pregnant and lactating women. Vitamin D has a role in bone health through calcium absorption and uptake by bones (Ref. 22). Deficiency results in inadequate bone mineralization or demineralization of the skeleton including rickets, osteomalacia, and osteoporosis (Ref. 22). Therefore, we tentatively conclude that vitamin D has public health significance in children 1 through 3 years of age and pregnant women based on the high prevalence of inadequate intakes of vitamin D and its important role in bone development and health (Ref. 22). In addition, in 2008, we authorized a health claim for calcium and vitamin D intake and reduced risk of osteoporosis (§ 101.72), signifying vitamin D's critical role in the risk reduction of this chronic disease for individuals 2 years of age and older. We also tentatively conclude that vitamin D is of public health significance for infants 7 through 12 months of age based on its importance for growth and development during infancy.

We are proposing to require the declaration of potassium on foods for the general population (see proposed § 101.9(c)(8)(ii) and section II.H.1.). The AI for infants is based on average potassium intake from breast milk and/or complementary foods. The AI for the other life-stage and gender groups is set at a level to maintain blood pressure, reduce the adverse effects of sodium chloride intake on blood pressure, and reduce the risk of recurrent kidney stones (Ref. 21).

Our analysis of NHANES 2003-2006 shows that 99 percent of infants ages 7 to 12 months have usual potassium intakes above the AI (table 3). Only 7 percent of children 1 through 3 years of age (table 4) and 4 percent of pregnant women (table 5) had usual potassium intakes above the AI from conventional foods or conventional foods plus dietary supplements, indicating that the adequacy of intakes is very low. In the absence of a sensitive biochemical indicator of potassium nutritional status, we could not consider biomarker data to inform the determination of prevalence of potassium deficiency. In 2000, a FDAMA notification for a health claim about potassium, blood pressure, and stroke was submitted to us under section 403(r)(2)(g) of the FD&C Act (Ref. 114). Foods may bear the following claim "Diets containing foods that are good sources of potassium and low in sodium may reduce the risk of high blood pressure and stroke," on the label or labeling of any food product that meets the eligibility criteria described in the notification and meets the general requirements for a health claim (§ 101.14(e)(6)). This health claim pertains to the general population 2 years of age and older. Thus, we recognize the importance of potassium in the risk reduction of these chronic diseases for children 2 years of age and older. Therefore, we tentatively conclude that potassium is of public health significance to children 1 through 3 years of age, and pregnant and lactating women. We have no basis to conclude that the public health significance of potassium among infants 7 through 12 months of age would be different than the science-based evidence for children 1 through 3 years of age and consider it important to establish healthy dietary practices for later life. Because of the benefits of adequate potassium intake in lowering blood pressure, data indicating low likelihood of potassium adequacy, and importance of establishing healthy dietary practices for later life, we tentatively conclude that potassium is a nutrient of public

health significance for infants 7 through 12 months of age, children 1 through 3 years of age, and pregnant and lactating women.

We are proposing to require the labeling of vitamin D and potassium on foods represented or purported to be specifically for infants 7 through 12 months of age, children 1 through 3 years of age, or pregnant and lactating women based on the quantitative intake recommendations for vitamin D and potassium and the public health significance of these nutrients. Consequently, we are not providing for any exceptions for these subpopulations from the general requirement for declaration of vitamin D and potassium in proposed § 101.9(c)(8)(ii).

c. Voluntary Declaration of Vitamin A and Vitamin C--We are proposing to no longer require the declaration of vitamin A and vitamin C on foods for the general population (see section II.H.1.). None of the DRIs (AIs or RDAs) for vitamin A were based on chronic disease risk, a health related-condition, or health-related physiological endpoints. One comment to the 2007 ANPRM stated that intakes of vitamins A and C among young children appear to be adequate (Ref. 148) and supported voluntary declaration of these nutrients in the labeling of foods for this subpopulation.

Our analysis of data from NHANES 2003-2006 shows that less than 2 percent of children had usual vitamin A intakes below the EAR from conventional foods or conventional foods plus dietary supplements (table 4). While 36 percent of pregnant women had usual intakes below the EAR from conventional foods and 22 percent had usual intakes below the EAR for conventional foods plus dietary supplements, only 1 percent of these women had serum vitamin A levels that were considered to be indicative of a vitamin A deficiency (table 5).

While quantitative intake recommendations are available for vitamins A and C, neither of these vitamins is considered to have public health significance for children 1 through 3 years of

age and pregnant women. There is a very low prevalence of inadequate intakes of vitamins A and C or inadequate status among children 1 through 3 years of age or pregnant women, and we have no evidence to indicate that this would be different for infants or lactating women. Therefore, we tentatively conclude that vitamin A and vitamin C are not of public health significance among infants 7 through 12 months of age, children 1 through 3 years of age, and pregnant and lactating women. Thus, we agree with a comment that supported voluntary declaration of vitamins A and C in the labeling of foods for young children. An AI for older infants was provided by the IOM with the assumption that vitamin A and vitamin C intakes are adequate during infancy. Accordingly, similar to our proposal for voluntary declaration of vitamins A and C in the labeling of foods for the general population, we are proposing to permit, but not require, the declaration of vitamin A and vitamin C on foods represented and purported to be specifically for infants 7 through 12 months, children 1 through 3 years of age, or pregnant and lactating women. As for other voluntary nutrients, the declaration of these nutrients would be required when these nutrients are added as nutrient supplements or claims are made about them (proposed § 101.9(c)(8)(ii)).

d. Voluntary Declaration of Other Vitamins and Minerals--As discussed in section II.H.3., for the general population, we are proposing to permit the voluntary declaration of vitamin E, vitamin K, vitamin B<sub>6</sub>, vitamin B<sub>12</sub>, thiamin, riboflavin, niacin, folate, biotin, pantothenic acid, phosphorus, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, and choline (proposed § 101.9(c)(8)(ii)). Vitamins and minerals other than iron, calcium, vitamin D and potassium for infants either have DRIs that are not based on chronic disease risk, health-related conditions, or health-related physiological endpoints or are not shown to have public health significance due to the prevalence of a

clinically relevant nutrient deficiency. For infants 7 to 12 months, children 1 through 3 years of age, and pregnant and lactating women, we tentatively conclude that the essential vitamins and minerals, other than iron, calcium, vitamin D and potassium, do not have public health significance and there is no basis for the declaration of these nutrients to be different from that proposed for the general population. Accordingly, proposed § 101.9(c)(8)(ii) would allow the voluntary declaration of vitamin E, vitamin K, vitamin B<sub>6</sub>, vitamin B<sub>12</sub>, thiamin, riboflavin, niacin, folate, biotin, pantothenic acid, phosphorus, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, and choline on foods represented or purported to be specifically for infants 7 to 12 months, children 1 through 3 years of age, or pregnant and lactating women, under the requirements of this section, unless they are added to foods as a nutrient supplement or if the label or labeling makes a claim about them, in which case the nutrients would have to be declared.

#### 5. DRVs and RDIs for Infants 7 Through 12 Months of Age

FDA regulations do not include DRVs or RDIs for nutrients for infants 7 through 12 months of age, except an RDI for protein of 14 g for infants. We reviewed scientific evidence and recommendations, as well as comments in response to the 2007 ANPRM to consider establishing DRVs and RDIs for nutrients for infants 7 through 12 months of age and to consider revisions to the current RDI for protein.

a. Calories--We have not established a reference calorie intake level for infants and children less than 2 years of age. For the general population, a reference calorie intake level is necessary when using a percent of calories approach to calculating the DRV for nutrients, such as total fat and carbohydrate. There is no quantitative intake recommendation for calories for infants and we are not aware of other scientific data and information on which we could rely to

establish that level. Therefore, we are not proposing to establish a reference calorie intake level for infants 7 to 12 months.

b. Total Fat--The IOM set an AI of 30 g/d for fat for infants 7 through 12 months of age based on the average intake of human milk and complementary foods (Ref. 49). There was no AI available in 1993. The current AI provides a basis on which we can determine an appropriate DRV for total fat for this subpopulation that can assist consumers in maintaining healthy dietary practices among this subpopulation. Therefore, we are proposing to amend § 101.9(c)(9) to include a DRV of 30 g for fat for infants 7 through 12 months of age.

c. Saturated Fat, Trans Fat, Cholesterol, Dietary Fiber and Sugars--There are no quantitative intake recommendations from U. S. consensus reports available for saturated fat, trans fat, cholesterol, dietary fiber, and sugars for infants. We are not aware of other scientific data and information on which we could rely to establish DRVs for these nutrients for infants 7 through 12 months of age. Accordingly, we are not proposing to establish DRVs for these nutrients for infants 7 through 12 months of age.

d. Polyunsaturated Fat, Monounsaturated Fat, Insoluble Fiber, Soluble Fiber, Insoluble Fiber, Added Sugars, and Sugar Alcohols--Quantitative intake recommendations from U. S. consensus reports are not available for polyunsaturated fat, monounsaturated fat, insoluble fiber, soluble fiber, added sugars, or sugar alcohols for infants. We are not aware of other scientific data and information on which we could rely to establish DRVs for these nutrients for this subpopulation. Accordingly, we are not proposing to establish DRVs for these nutrients for infants 7 through 12 months of age.

e. Total Carbohydrate--The IOM has set an AI of 95 g/d for carbohydrates for infants 7 through 12 months of age based on the average intake of human milk and complementary foods

(Ref. 68). There was no AI available in 1993. The current AI provides a basis on which we can determine an appropriate DRV for total carbohydrate for this subpopulation that can assist consumers in maintaining healthy dietary practices among this subpopulation. Therefore, we are proposing to amend § 101.9(c)(9) to establish a DRV of 95 g for total carbohydrate for infants 7 through 12 months of age.

f. Protein--The DV for protein for infants is an RDI, rather than a DRV. Before 1993, we established the RDIs for protein for all age groups based on the 1989 RDA. In 1993, we changed the RDI for protein for the general population to a DRV in response to comments that suggested the DV for protein should be consistent with the "percent of calories" approach used for the other energy-yielding macronutrients, total fat and total carbohydrate (58 FR 2206 at 2216). However, we retained the RDI for infants, and based it on the highest 1968 RDA value (14 g/d for infants), to be consistent with a population-coverage approach (58 FR 2206 at 2216).

We find no reason to change the approach of using the RDI for infants 7 through 12 months. However, we consider it appropriate to revise the RDI to rely on current quantitative intake recommendations. In 2002, the IOM established an RDA for infants 7 through 12 months of 1.2 g/kg/d based on nitrogen balance studies and using a reference body weight of 9 kg (Ref. 84). This reference body weight is also consistent with current growth charts for infants (Ref. 156). The value  $1.2\text{g/kg/g}\times 9\text{ kg}$  equals 10.8 g/d or a rounded value of 11 g/d. In addition, protein intakes are well above the current and proposed RDI. Mean protein intake for infants 6 to 11 months of age was 22 g/d (Ref. 150), well above the RDA of 11 g/d. Accordingly, we are proposing to revise § 101.9(c)(9) to establish an RDI of 11 g for protein for infants 7 through 12 months of age.

g. Sodium--For the general population, we are proposing to establish a DRV for sodium based on the IOM's UL. (section II.F.). The IOM did not set a UL for sodium for infants 7 through 12 months of age due to insufficient data on adverse effects of chronic overconsumption in this age group (Ref. 10). We are not aware of other scientific data and information on which we could rely to establish a DRV for sodium for this subpopulation. Therefore, we are not proposing a DRV for sodium for infants 7 through 12 months of age.

h. Fluoride--As discussed in section II.G., although the IOM set an AI for fluoride, the AIs for infants 7 through 12 months and children 1 through 3 years are close to the EPA benchmarks for total fluoride intake (Ref. 92). We are not proposing a DRV for fluoride for use in the labeling of foods for the general population because of a concern about excess intakes associated with dental fluorosis (section II.G.). Therefore, we tentatively conclude that a DRV for fluoride is not warranted for infants 7 through 12 months. The use of such a DRV to calculate percent DV may have the unintended effect of consumers selecting foods with higher fluoride amounts, which are not necessary or advised. Accordingly, we are not proposing to establish a DRV for fluoride for infants 7 through 12 months of age.

i. Vitamins and Minerals--As noted previously in the introduction to section II.K., while not included in current regulations, the preamble to the 1993 DRV/RDI final rule provides a table listing RDIs for infants (58 FR 2206 at 2213), which is also provided in FDA's Food Labeling Guide (Ref. 144). We reviewed current quantitative intake recommendations for vitamins and minerals for infants and considered comments received in response to the 2007 ANPRM (Ref. 47) to determine appropriate RDIs for vitamins and minerals to be established in regulations for infants 7 through 12 months of age.

We consider it important to establish RDIs for infants 7 through 12 months of age because infants in this age range transition from a diet of mostly breast milk and infant formula to infant cereal and baby foods (Ref. 147 p. 71) and labeling foods for this subpopulation with percent DV declarations can assist parents in making nutritious food choices. The DRIs (AIs and RDAs) provide a basis on which to determine RDIs for vitamins and minerals for this subpopulation. We consider it appropriate to use RDAs and, in the absence of RDAs, AIs to determine appropriate micronutrient RDIs for infants. While there is more certainty with RDAs than AIs, both RDAs and AIs are sufficient for setting RDIs, because they both represent intake levels that are expected to meet or exceed the nutrient needs of the majority of infants (Ref. 157).

We also considered and rejected an approach, as suggested by a comment, where the highest reference value available would be used for each nutrient, irrespective of whether it is an RDI based on the 1968 RDAs, a current RDA, or a current AI. The IOM established DRIs based on scientific knowledge that update and supersede previous RDA recommendations. Because DRIs are available for infants 7 through 12 months of age, we are proposing to use these current quantitative intake recommendations (i.e., AIs and RDAs) for setting RDIs for infants.

Accordingly, we are proposing to amend § 101.9(c)(8)(iv) to include a listing of RDIs for vitamin A, vitamin C, vitamin D, vitamin E, vitamin K, vitamin B<sub>12</sub>, folate, choline, riboflavin, niacin, vitamin B<sub>6</sub>, calcium, iron, thiamin, biotin, pantothenic acid, phosphorous, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, and potassium for infants 7 months through 12 months of age.

We invite comment on the adequacy of the proposed RDIs for vitamins and minerals for older infants.

## 6. DRVs and RDIs for Children 1 Through 3 Years of Age

FDA regulations do not include DRVs or RDIs for nutrients for children 1 through 3 years of age, except an RDI for protein of 16 g for children less than 4 years of age. We reviewed scientific evidence and current recommendations, as well as comments in response to the 2007 ANPRM to consider establishing DRVs and RDIs for nutrients for this subpopulation and to consider revisions to the current RDI for protein.

a. Calories--We have not established a reference calorie intake level for nutrition labeling for children ages 1 through 3 years. Several comments to the 2007 ANPRM supported establishing a DV for calories specifically for young children 1 through 3 years of age. Citing the IOM and AAP/AHA caloric intake recommendations (Refs. 50 and 71), one comment recommended 1,050 calories as the DV for calories and supported rounding it down to 1,000 calories to facilitate use by consumers.

We consider it appropriate to establish a reference calorie intake level for children 1 through 3 years of age because, as discussed in this document, we are proposing to set DRVs using quantitative intake recommendations that are based on calories (e.g., total fat, saturated fat, and dietary fiber). Current recommendations from the IOM, AHA, AAP, and the 2010 DGA for caloric intake range from 800 to 900 calories/d for children 1 year old, approximately 1,000 calories/d for children 2 years of age, and from 1,000 to 1,200 calories/d for children 3 years of age (Refs. 6, 50, and 71). We consider that an average of the range of these caloric intake recommendations (800 to 1,200 calories/d), i.e., 1,000 calories/d, provides a reasonable reference calorie intake level. Therefore, we are proposing to amend § 101.9(c)(9) to provide a reference calorie intake level of 1,000 calories/d for children 1 through 3 years of age.

b. Total Fat--There is no DRV for total fat for children ages 1 through 3 years. One comment to the 2007 ANPRM recommended that 35 percent of the recommended 1,050 calories

or 41 g/d of fat be used to as the DRV for fat because it is the midpoint of the AAP/AHA recommendation and the IOM Acceptable Macronutrient Distribution Range (AMDR) for 1 through 3 year olds. We agree that 35 percent of calories from fat for children 1 through 3 years of age, the midpoint of the IOM AMDR of 30 to 40 percent, serves as an appropriate basis on which to set the DRV for total fat. This approach to calculating the DRV for total fat is consistent with our proposed approach to setting the DRV for total fat for the general population. Thirty-five percent is also consistent with AHA and AAP recommendations that 30 to 40 percent of calories consumed by children 12 through 24 months of age and 30 to 35 percent of calories consumed by children 24 through 48 months of age should come from fat (Ref. 71). Therefore, we tentatively conclude that 35 percent of total calories from fat (i.e., 39 g using the proposed reference calorie intake level of 1,000 calories/d) is an appropriate DRV for total fat for children 1 through 3 years of age. Accordingly, we are proposing to amend § 101.9(c)(9) to establish a DRV of 39 g for fat for children 1 through 3 years of age.

c. Saturated Fat, Trans Fat, and Cholesterol--There are no DRVs for saturated fat, trans fat, or cholesterol for children 1 through 3 years of age. Once comment to the 2007 ANPRM suggested using the midpoint of 10 to 15 percent of calories for saturated fat, 2 percent of calories for trans fat based on estimates of mean trans fat intake for the U. S. population 3 years of age and older, and less than or equal to 300 mg/d for cholesterol based on the 2005 DGA recommendation.

Cardiovascular disease is known to begin in childhood (Refs. 146 and 151). The 2010 DGA recommends that Americans 2 years of age and older consume less than 10 percent of calories from saturated fat and less than 300 mg/d of cholesterol (Ref. 6). Based on these recommendations, we tentatively conclude that it is appropriate to set a DRV of 10 g for

saturated fat, based on 10 percent of total calories from saturated fat and using the proposed reference calorie intake level of 1,000 calories/d which equals 11 g, rounded down to 10 g, and a DRV of 300 mg for cholesterol for children 1 through 3 years of age. The comment provided no rationale for using an upper range of 15 percent of calories from saturated fat. We have no information to indicate that applying the level of 10 percent of calories from saturated fat to this subpopulation is restrictive, as the comment asserted. Accordingly, we are proposing to amend § 101.9(c)(9) to establish a DRV of 10 g for saturated fat and a DRV of 300 mg for cholesterol for children 1 through 3 years of age.

Current recommendations from the IOM (Ref. 49) and 2010 DGA (Ref. 6) recommend keeping trans fat intake as low as possible but do not provide any specific appropriate levels of intake. Thus, consistent with our discussion in section II.B.3., we disagree with the comment that suggested setting a DRV for trans fat and, therefore, we are not proposing to establish a DRV for trans fat in response to this comment.

d. Polyunsaturated Fat, Monounsaturated Fat, Sugars, Added Sugars, Insoluble Fiber, Soluble Fiber, and Sugar Alcohols--There are no DRVs for polyunsaturated fat, monounsaturated fat, sugars, added sugars, insoluble fiber, soluble fiber, or sugar alcohol for children 1 through 3 years of age. One comment to the 2007 ANPRM recommended establishing a DV for n-3 polyunsaturated fatty acids ( $\alpha$ -linolenic acid) of 700 mg/d because  $\alpha$ -linolenic acid is essential to the human diet and children 1 through 3 years of age are below recommended intake levels. We disagree that a DRV should be set for n-3 polyunsaturated fatty acids for children 1 through 3 years of age for the same reasons that we are not proposing a DRV for these fatty acids for the general population (see section II.B.). We recognize the essential nature of  $\alpha$ -linolenic acid in the diet. The IOM based AIs for n-6 linoleic and n-3  $\alpha$ -linolenic

acid on U. S. median intake levels because of the lack of linoleic and  $\alpha$ -linolenic acid deficiency in non-institutionalized populations in the United States (Ref. 49).

For children 1 through 3 years of age, DRIs or other data and information are not available on which we could rely to establish DRVs for polyunsaturated fat, monounsaturated fat, sugars, added sugars, insoluble fiber, soluble fiber, and sugar alcohols. Therefore, we tentatively conclude that there is no basis for setting DRVs for these nutrients. Accordingly, we are not proposing DRVs for polyunsaturated fat, including  $n$ -3 or  $n$ -6 polyunsaturated fatty acids, monounsaturated fat, sugars, added sugars, soluble fiber, insoluble fiber, or sugar alcohols for children 1 through 3 years of age.

e. Total Carbohydrate--There is not a DRV for total carbohydrate for children 1 through 3 years of age. One comment to the 2007 ANPRM suggested that we establish a DV for carbohydrates using 59 percent of calories from carbohydrates, or 154 g using the method of calculation by difference.

As discussed in section II.D.1., we are proposing a DRV for total carbohydrate for the general population based on the percentage of calories in a 2,000 calorie diet remaining after the sum of the DRV for fat (30 percent) plus the DRV for protein (10 percent) have been subtracted. We also consider this method to be appropriate for setting a DRV for total carbohydrate for children 1 through 3 years of age. Total calories (100 percent) minus the proposed DRV for total fat (35 percent of calories) and the proposed DRV for protein (5 percent of calories) equals 60 percent of calories from total carbohydrate. A value of 60 percent of total calories from total carbohydrates also falls within the IOM AMDR recommendation of 45 to 65 percent of calories from carbohydrates for children 1 through 3 years of age. Therefore, we tentatively conclude that an appropriate DRV for total carbohydrate is 60 percent of calories (i.e., 150 g using the

proposed reference calorie intake level of 1,000 calories/d). Accordingly, we are proposing to amend § 101.9(c)(9) to set a DRV of 150 g for total carbohydrate for children 1 through 3 years of age.

f. Dietary Fiber--There is not a DRV for dietary fiber for children 1 through 3 years of age. One comment to the 2007 ANPRM recommended using 15 g/d as the basis of the DRV for dietary fiber, based on the AI of 14 g/1,000 calories and a 1,050 calorie diet. We agree that the AI of 14 g/1,000 calories for dietary fiber for children 1 through 3 years of age (Ref. 66) should be used to set a DRV for dietary fiber to be consistent with how other proposed DRVs are being set. Given that we are proposing a reference calorie intake level of 1,000 calories/d for this subpopulation, we are proposing to amend § 101.9(c)(9) to establish a DRV of 14 g for dietary fiber for children 1 through 3 years of age.

g. Protein--The RDI for protein for children less than 4 years of age was based on the 1989 RDA for protein of 16 g/d (§ 101.9(c)(7)(iii)). One comment to the 2007 ANPRM recommended maintaining the DV of 16 g for protein because the RDA for protein of 13 g/d for toddlers 1 through 3 years of age appears low relative to the amount of protein from a diet pattern consistent with dietary guidance from AAP/AHA.

We consider it appropriate to determine whether changes are necessary to the current RDI taking into account current recommendations and protein intakes. Protein intakes are well above the current RDI. Mean protein intake for children 12 to 23 months of age was 44 g/d (Ref. 150), well above the RDA of 13 g/d and the midpoint of the AMDR of 5 to 20 percent calories from protein (i.e., 12.5 percent of calories from protein or 31 g/d) (Ref. 84). The protein AMDR for children 1 through 3 years of age is 5 to 20 percent of calories and the RDA is approximately 5 percent of calories (Ref. 84). While the RDA is lower than the amount of protein consistent

with guidance from AAP/AHA, we explain in section II.B.2.c. that we do not consider the menu modeling approach used to develop this guidance appropriate to determine DRVs because it does not permit the selection of DRVs that are based on scientific evidence related to actual public health outcomes. In light of the proposed reference calorie intake level and the approaches used for the proposed DRVs for fat and carbohydrate that are based on percent of calories, we tentatively conclude that, as with the general population, the DV for protein for children 1 through 3 years of age should be a DRV, rather than an RDI (using the RDA). Therefore, we tentatively conclude that a DRV for protein should be based on 5 percent of 1,000 calories or 50 calories which equals 12.5 g or, when rounded up, is 13 g. Accordingly, we are proposing to amend § 101.9(c)(7)(iii) to establish a DRV for protein of 13 g for children 1 through 3 years of age.

h. Sodium--For the general population, we are proposing to establish a DRV based on the UL for sodium (section II.F.). There is no DRV for sodium for children 1 through 3 years of age. Two comments to the 2007 ANPRM recommended basing the DRV for sodium on the IOM's UL of 1,500 mg/d for children 1 through 3 years of age to be consistent with recommendations from AAP and AHA (Ref. 71).

The IOM derived the UL for children 1 through 3 years of age by extrapolation from the adult UL of 2,300 mg/d based on observational studies showing that blood pressure increases with age into adulthood and the recognition that risk factors for CVD, such as high blood pressure and atherosclerosis, occur in childhood (Ref. 10). We agree with the comments noting that 1,500 mg is an appropriate DRV for sodium for children 1 through 3 years of age.

Consistent with the proposed approach for the general population, we are proposing to amend

§ 101.9(c)(8)(iv) to establish a DRV of 1,500 mg for sodium for children 1 through 3 years of age.

i. Fluoride--There is not a DV for fluoride for children 1 through 3 years of age. One comment to the 2007 ANPRM suggested that fluoride should not have a DV because it is not found abundantly in food. We disagree with this comment. Whether a nutrient is found abundantly in food is not a consideration for FDA in setting DVs. The IOM recognized fluoride as a trace mineral that is important for public health by setting an AI based on evidence of its role in reducing the risk of dental caries.

However, we tentatively conclude that a DRV should not be established for fluoride. Although the IOM set an AI for fluoride, the AI for children 1 through 3 years of age is close to the EPA benchmarks for maximum total fluoride intake (Ref. 92). In addition, we are not proposing a DRV for the general population because of concern about excess intakes associated with dental fluorosis (see section II.G.). The use of such a DRV to calculate percent DV may have the untoward effect of consumers selecting foods with higher fluoride amounts, which are not necessary or advised. Therefore, we tentatively conclude that a DRV for fluoride is not warranted for children 1 through 3 years of age. Accordingly, we are not proposing a DRV for fluoride for children 1 through 3 years of age.

j. Vitamins and Minerals--As explained earlier, while not included in our regulations, the preamble to the 1993 DRV/RDI final rule provides a table listing RDIs for children less than 4 years of age (58 FR 2206 at 2213), which is also provided in FDA's Food Labeling Guide (Ref. 144). We reviewed current quantitative intake recommendations for vitamins and minerals for infants and considered comments received in response to the 2007 ANPRM (Ref. 47) to determine appropriate RDIs for vitamins and minerals for children 1 through 3 years of age.

The IOM's quantitative intake recommendations (AIs and RDAs) provide a basis on which to determine RDIs for vitamins and minerals for this subpopulation. In addition, where data on functional indicators of nutritional status were available, the IOM relied on such data and determined that available evidence was sufficient to establish appropriate RDAs and AIs for vitamins and minerals for this subpopulation. Therefore, we disagree with a comment to the 2007 ANPRM that suggested that more population-specific data based on functional indicators of nutritional status are needed before establishing the RDIs for vitamins and minerals.

We consider it appropriate to use RDAs and, in the absence of RDAs, AIs to determine appropriate micronutrient RDIs for children 1 through 3 years of age. As such, we agree with comments that suggested using RDAs to determine the RDIs for selenium and vitamin E and AIs to determine the RDIs for choline, vitamin K, and manganese, which do not have established RDAs. The RDA, when available, is the best estimate of an intake level that will meet the nutrient goals of practically all consumers who would use the Nutrition Facts label. AIs have less certainty than RDAs, but they represent goals for nutrient intake for individuals and provide the best estimate based on current science for use in setting RDIs for such nutrients.

Finally, we disagree with comments suggesting we use 1,800 or 2,000 mg/d potassium as the basis for the RDI for potassium because it is inconsistent with the proposed approach for the general population. The comments did not explain why data collection on mean potassium intake should be the basis for the DV in lieu of the AIs and RDAs. In addition, promoting the development of eating patterns that will be associated with adequate potassium intake later in life is important because chronic conditions such as elevated blood pressure, bone demineralization, and kidney stones likely result from inadequate potassium intakes over an extended period of

time, including childhood (Ref. 136). The AI for potassium is 3,000 mg/d and we consider it an appropriate basis for establishing a RDI for potassium for children 1 through 3 years of age.

Therefore, using the RDAs and AIs, we are proposing to amend § 101.9(c)(8)(iv) to establish RDIs as set forth previously for vitamin A, vitamin C, vitamin D, vitamin E, vitamin K, vitamin B<sub>12</sub>, folate, choline, riboflavin, niacin, vitamin B<sub>6</sub>, calcium, iron, thiamin, biotin, pantothenic acid, phosphorous, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, and potassium for children 1 through 3 years of age.

We invite comment on the adequacy of the proposed RDIs for vitamins and minerals for children 1 through 3 years of age.

## 7. DRVs and RDIs for Pregnant and Lactating Women

a. Calories--The reference calorie intake of 2,000 used for the general population applies to pregnant and lactating women (§ 101.9(c)(9)). The calorie needs for pregnant and lactating women are similar to the general population and few products are purported for pregnant and lactating women. Therefore, we tentatively conclude that it is appropriate to establish a reference calorie intake level for setting DRVs for pregnant and lactating women that is the same as for the general population. Accordingly, we are proposing to use the 2,000 reference calorie intake level for setting DRVs for pregnant and lactating women (§ 101.9(c)(9)).

b. Total Fat, Saturated Fat, Cholesterol, Total Carbohydrate, Sodium, and Dietary Fiber--FDA regulations do not provide DRVs for total fat, saturated fat, cholesterol, total carbohydrate, sodium, and dietary fiber for pregnant and lactating women. Quantitative intake recommendations for total fat, saturated fat, cholesterol, total carbohydrate, sodium, and dietary fiber for pregnant and lactating women are generally similar to the general population (Refs. 6 and 23). Therefore, we tentatively conclude that the DRVs for total fat, saturated fat, cholesterol,

total carbohydrate, sodium, and dietary fiber for pregnant and lactating women should remain the same as for the general population. Accordingly, we are proposing to amend § 101.9(c)(9) to establish DRVs for pregnant and lactating women using the proposed DRVs for the general population for total fat, saturated fat, cholesterol, total carbohydrate, sodium, and dietary fiber.

c. Trans Fat, Polyunsaturated Fat, Monounsaturated Fat, Soluble Fiber, Insoluble Fiber, Sugars, Added Sugars, and Sugar Alcohols--There are no DRVs for trans fat, polyunsaturated fat, monounsaturated fat, soluble fiber, insoluble fiber, sugars, added sugars, or sugar alcohol for pregnant and lactating women. As discussed in sections II.B. and II.D., we are not proposing DRVs for these nutrients for the general population because of a lack of quantitative intake recommendations. Similarly, quantitative intake recommendations are lacking for these nutrients for pregnant and lactating women. Therefore, we are not proposing to establish DRVs for trans fat, polyunsaturated and monounsaturated fat, soluble fiber, insoluble fiber, sugars, added sugars, or sugar alcohols for pregnant and lactating women.

d. Protein--FDA established RDIs of 60 g protein for pregnant women and 65 g protein for lactating women (§ 101.9(c)(7)(iii)) based on the highest 1989 RDAs for pregnant and lactating women (58 FR 2206 at 2216). The IOM established 71 g/d protein as the RDA for pregnant and lactating women based on the needs for maternal and fetal development and human milk production. Because the RDA for protein during both pregnancy and lactation is the same (Ref. 84) and given that most foods represented or purported to be specifically for pregnant women are also represented or purported to be specifically for lactating women, we tentatively conclude that it is appropriate to establish a single RDI of 71 g applicable to both pregnant and lactating women. We tentatively conclude that the DV for protein for pregnant and lactating women should remain an RDI (using the RDA) instead of a DRV because the DRV approach

used to calculate protein for the general population based on 10 percent of 2,000 calories, which equals 50 g of protein/d, falls short of the recommended protein needs of pregnant and lactating women of 71 g/d. Therefore, we are proposing to amend § 101.9(c)(7)(iii) to establish an RDI of 71 g for protein for pregnant and lactating women.

e. Fluoride--There is no DRV for fluoride for the general population or for pregnant and lactating women. While an AI has been established for fluoride, we are not proposing to establish a DRV for fluoride for the general population for the reasons discussed in section II.G. Similarly, because the AI for fluoride for pregnant and lactating women is not different from the general population (Ref. 90), we are not proposing a DRV for fluoride for pregnant and lactating women.

f. Vitamins and Minerals--While not included in FDA regulations, the preamble to the 1993 DRV/RDI final rule provides a table listing RDIs for pregnant and lactating women (58 FR 2206 at 2213), which is also provided in FDA's food labeling guide (Ref. 144). We reviewed current quantitative intake recommendations for vitamins and minerals for pregnant and lactating women and considered comments received in response to the 2007 ANPRM (Ref. 47) to determine appropriate RDIs for vitamins and minerals for pregnant and lactating women.

For the same reasons stated for the general population (see section II.I.), we consider it appropriate to establish RDIs for pregnant and lactating women for vitamins and minerals that have DRIs, using population-coverage RDAs and AIs, instead of population-weighted EARs. In addition, we are proposing to establish a single set of RDIs intended for both pregnant women and lactating women because nutrient needs during pregnancy and lactation are similar (Refs. 16,17,21,22,140). Moreover, most foods represented or purported to be specifically for pregnant women are, at the same time, represented or purported to be specifically for lactating women

and, as such, using one set of RDIs would address practical concerns related to limited space on food labels.

Therefore, we are proposing to amend § 101.9(c)(8)(iv) to establish RDIs as set forth previously for vitamin A, vitamin C, vitamin D, vitamin E, vitamin K, vitamin B<sub>12</sub>, folate, choline, riboflavin, niacin, vitamin B<sub>6</sub>, calcium, iron, thiamin, biotin, pantothenic acid, phosphorous, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, and potassium for pregnant and lactating women.

Table 3.--Prevalence of Nutrient Inadequacy and Adequacy (From Conventional Foods and Water) and From Total Intake (Conventional Foods, Water, and Supplements) of U.S. Infants 7 Through 12 Months of Age<sup>1</sup>

Nutrients	EAR <sup>3</sup>	Usual Nutrient Intake <sup>2</sup>	
		% Below the EAR <sup>4</sup>	
		Food	Total Intake
Iron	6.9 mg	17.8	3.7
Zinc	2.5 mg	0.1	0.1
	AI <sup>3</sup>	% Above AI <sup>5</sup>	
Choline	150 mg	23.5	23.5
Folate	80 mcg	100	100
Niacin	4 mg	99.9	99.9
Riboflavin	0.4 mg	100	100
Thiamin	0.3 mg	99.9	99.9
Vitamin A	500 mcg	86.9	87.5
Vitamin B <sub>6</sub>	0.3 mg	99.9	99.9
Vitamin B <sub>12</sub>	0.5 mg	99.8	99.8
Vitamin C	50 mg	90.1	94
Vitamin D	10 mcg	28.7	33.6
Vitamin E	5 mcg	67	70.6
Vitamin K	2.5 mcg	100	100
Calcium	260 mg	99.6	99.6
Copper	220 mcg	100	100
Magnesium	75 mg	97.6	97.6

Phosphorus	275 mg	98.9	98.9
Potassium	700 mg	98.8	98.8
Selenium <sup>6</sup>	20 mcg	9.9	9.9

<sup>1</sup>All prevalence of nutrient inadequacy or adequacy and status biomarker data is based on NHANES 2003-2006 except for vitamin D and choline (NHANES 05-08).

<sup>2</sup>Usual nutrient intake distributions from conventional foods are determined using the National Cancer Institute statistical method for all nutrients except iron (see footnote 9 to table 1 and Ref. 48 ).

<sup>3</sup>The DRIs (Estimated Average Requirements (EARs) and Adequate Intakes (AIs)) for infants ages 7-12 months are established by the Institute of Medicine

[http://www.iom.edu/Activities/Nutrition/SummaryDRIs/~media/Files/Activity%20Files/Nutrition/DRIs/New%20Material/2\\_%20RDA%20and%20AI%20Values\\_Vitamin%20and%20Elements.pdf](http://www.iom.edu/Activities/Nutrition/SummaryDRIs/~media/Files/Activity%20Files/Nutrition/DRIs/New%20Material/2_%20RDA%20and%20AI%20Values_Vitamin%20and%20Elements.pdf).

<sup>4</sup>The EAR cut-point method was used to compare usual nutrient intakes to the EAR to determine the prevalence of nutrient inadequacy for iron and zinc. For iron, refer to Table I-5 Probability of inadequate iron intakes (Refs. 100 and 158).

<sup>5</sup>For nutrients with an AI, prevalence of nutrient adequacy was determined when usual nutrient intakes are at or above the AI.

<sup>6</sup>We did not receive any comments for this nutrient (for which voluntary declaration is permitted) in response to the ANPRM. In addition, dietary intake and/or biomarker data were not provided in NHANES database for chromium, biotin, iodine, pantothenic acid, molybdenum, manganese and chloride and, therefore, these nutrients are not listed in this table.

Table 4. Prevalence of Nutrient Inadequacy and Adequacy (From Conventional Foods and Water and Total Intake (Conventional Foods, Water, and Supplement) and Status Biomarkers of the U.S. Population of Children 1 Through 3 Years of Age<sup>1</sup>

Nutrient	EAR <sup>3</sup>	Usual Nutrient Intake <sup>2</sup>			
		% below EAR <sup>4</sup>		Status Biomarker	
		Food	Total Intake	Biomarker Cutoff	% Below Cutoff
Folate	120 mcg	0.1	0.1	Serum folate < 2 ng/mL RBC folate < 95 ng/mL	0.01 0.17
Niacin	5 mg	0.6	0.6	N/A	N/A
Riboflavin	0.4 mg	0	0	N/A	N/A
Thiamin	0.4 mg	0	0	N/A	N/A
Vitamin A	210 mcg	1.9	1.5	N/A	N/A
Vitamin B <sub>6</sub>	0.4 mg	1.5	1.1	Serum B <sub>6</sub> (pyridoxal 5' phosphate) < 20 nmol/L	2.57
Vitamin B <sub>12</sub>	0.7 mcg	0	0	Serum B <sub>12</sub> < 200 pg/mL	0.2
Vitamin C	13 mg	1.9	1.3	N/A	N/A
Vitamin D	10 mcg	82.0	66.5	Serum 25(OH)D < 50 nmol/L < 40 nmol/L < 30 nmol/L	8.2 2.9 0.8

Vitamin E	5 mg	84.6	61.6	Serum E < 516 mcg/dL	1.3
Calcium	500 mg	11.7	11.7	N/A	N/A
Copper	260 mcg	0.2	0.2	NA	NA
Iron	3 mg	1.0	0.42	<sup>5</sup> Serum ferritin < 12 mcg/L (99-02)	17.7
				Iron deficiency (Ferritin model, 99-02)	7.9
				Anemia (99-02)	1.8
				Serum ferritin < 12 mcg/L (03-06)	23.3
				Iron deficiency (Body iron model, 03-06)	9.5
Magnesium	65 mg	0	0	N/A	N/A
Phosphorus	380 mg	0.2	0.2	N/A	N/A
Selenium <sup>6</sup>	17 mcg	0	0	NA	NA
Zinc	2.5 mg	1.4	1.2	NA	NA
	AI <sup>3</sup>	% Above AI <sup>7</sup>			
Choline	200 mg	46.4	48.5	N/A	N/A
Potassium	3000 mg	6.5	6.5	N/A	N/A
Vitamin K	30 mcg	50.9	51.2	NA	NA

N/A = Data is not available in NHANES; mg = milligrams; mcg = micrograms.

<sup>1</sup> All prevalence of nutrient adequacy or inadequacy and status biomarker data is based on NHANES 2003-2006 except for vitamin D and choline intakes (2005-2008); serum pyridoxal-5'-phosphate (2005-2006); serum tocopherol for age 3 years (1999-2002), and serum ferritin (1999-2002).

<sup>2</sup> Usual nutrient intake distributions from conventional foods are determined using the National Cancer Institute statistical method for all nutrients except iron (see footnote 9 to table 1 and Ref. 48).

<sup>3</sup> The DRIs (Estimated Average Requirements (EARs) and Adequate Intakes (AIs)) for children 1-3 years of age are established by the Institute of Medicine. Units are in mg/d or mcg/d

[http://www.iom.edu/Activities/Nutrition/SummaryDRIs/~media/Files/Activity%20Files/Nutrition/DRIs/New%20Material/2\\_%20RDA%20and%20AI%20Values\\_Vitamin%20and%20Elements.pdf](http://www.iom.edu/Activities/Nutrition/SummaryDRIs/~media/Files/Activity%20Files/Nutrition/DRIs/New%20Material/2_%20RDA%20and%20AI%20Values_Vitamin%20and%20Elements.pdf)

<sup>4</sup> The EAR cut-point method was used to compare usual nutrient intakes to the EAR to determine the prevalence of nutrient inadequacy. For iron, refer to Table 1-5 Probability of inadequate iron intakes (Ref. 100).

<sup>5</sup> Serum ferritin analysis changed from the Biorad assay to the Roche assay in 2003. Serum ferritin for 2003-2006 using the Biorad assay was adjusted to be comparable to those 2004-2006 data using the Roche assay. Iron deficiency based on the ferritin model is calculated using 2 out of 3 cutoffs of iron deficiency variables (transferrin saturation, serum ferritin, and erythrocyte protoporphyrin, NHANES 1999-2002) (Refs. 155 and 159). Anemia was based upon iron deficiency criteria (ferritin model) and a low hemoglobin level. Iron deficiency based on the iron body model is calculated from the log ratio of transferrin receptor to ferritin using NHANES 2003-2006 data. NHANES 1999-2002 did not measure transferrin receptor; therefore body iron model could not be analyzed for this time frame. NHANES 2003-2006 did not measure all iron biomarkers for all ages, thus serum ferritin, body iron model or ferritin model could not be analyzed for all ages during this time period.

<sup>6</sup> We did not receive any comments for this nutrient (for which voluntary declaration is permitted) in response to the ANPRM. In addition, dietary intake and/or biomarker data were not provided in NHANES database for chromium, biotin, iodine, pantothenic acid, molybdenum, manganese and chloride and, therefore, these nutrients are not listed in this table.

<sup>7</sup>For nutrients with an AI, prevalence of nutrient adequacy was determined when usual nutrient intakes are at or above the AI.

Table 5.--Prevalence of Nutrient Inadequacy and Adequacy (From Conventional Foods and Water) and Total Intake (Conventional Foods, Water, and Supplement) and Status Biomarkers of the U.S. Population of Pregnant Women 14-50 Years of Age<sup>1</sup>

Nutrient	Weighted EAR <sup>3</sup>	Usual Nutrient Intake <sup>2</sup>			
		% below EAR <sup>4</sup>		Status Biomarker	
		Food	Total Intake	Biomarker Cutoff	% Below Cutoff
Folate	520 mcg	39.6	27.5	Serum folate < 2 ng/mL RBC folate < 95 ng/mL	0.28  0
Niacin	14 mg	3.7	2.6	N/A	N/A
Riboflavin	1.2 mg	3.6	3.1	N/A	N/A
Thiamin	1.2 mg	10.4	6.1	N/A	N/A
Vitamin A	549 mcg	36.4	22	Serum A < 20 mcg/mL	1.0
Vitamin B <sub>6</sub>	1.6 mg	28.3	15.7	Serum B <sub>6</sub> (Pyridoxal 5' phosphate) < 20 nmol/L	0
Vitamin B <sub>12</sub>	2.2 mcg	1.6	1.1	Serum B <sub>12</sub> < 200 pg/mL	4.1
Vitamin C	70 mg	21.7	11.2	Serum C < 11.4 µmol/L	0.4
Vitamin D	10 mcg	87.6	47.6	Serum 25(OH)D < 50 nmol/L < 40 nmol/L < 30 nmol/L	16.9 6.4 3.7
Vitamin E	12 mg	94.8	51	Serum E < 516 mcg/dL	0.6
Calcium	835 mg	20.7	18.9	N/A	N/A
Copper	0.79 mcg	4.4	4.1	N/A	N/A
Iron	22 mg	5.3	3.71	Serum ferritin < 15 mcg/L <sup>5</sup> Iron deficiency -Body iron model -Ferritin model Anemia	26.1  16.4 25.1 12.8
Magnesium	295 mg	57.2	55.0	N/A	N/A
Phosphorus	583 mg	0.3	0.3	N/A	N/A
Selenium <sup>6</sup>	49 mcg	0.7	0.7	N/A	N/A
Zinc	9.5 mg	15.9	12.8	N/A	N/A

	Weighted AI <sup>3</sup>	% Above AI <sup>7</sup>			
Choline	450 mg	13.5	13.6	N/A	N/A
Potassium	4700 mg	3.9	3.9	N/A	N/A
Vitamin K <sup>6</sup>	89 mcg	34.5	36.1	N/A	N/A

N/A = Data is not available in NHANES; mg = milligrams; mcg = micrograms.

<sup>1</sup>All prevalence of nutrient adequacy or inadequacy and biomarker data is based on NHANES 2003-2006 except for vitamin D and choline intakes (2005-2008); serum pyridoxal-5'-phosphate (2005-2006); serum tocopherol (1999-2002), and serum ferritin (1999-2002). Biomarker data are for pregnant women 12 through 49 years of age.

<sup>2</sup>Usual nutrient intake distributions from conventional foods are determined using the National Cancer Institute statistical method for all nutrients except iron (see footnote 9 to table 1 and Ref. 48).

<sup>3</sup>The DRIs (Estimated Average Requirements (EARs) and Adequate Intakes (AIs)) for pregnant women 14-50 years of age are established by the Institute of Medicine. Units are in mg/d or mcg/d

[http://www.iom.edu/Activities/Nutrition/SummaryDRIs/~media/Files/Activity%20Files/Nutrition/DRIs/New%20Material/2\\_%20RDA%20and%20AI%20Values\\_Vitamin%20and%20Elements.pdf](http://www.iom.edu/Activities/Nutrition/SummaryDRIs/~media/Files/Activity%20Files/Nutrition/DRIs/New%20Material/2_%20RDA%20and%20AI%20Values_Vitamin%20and%20Elements.pdf)

<sup>4</sup>The EAR cut-point method was used to compare usual nutrient intakes to the EAR to determine the prevalence of nutrient inadequacy. For iron, refer to Table I-5 Probability of inadequate iron intakes (Ref. 100).

<sup>5</sup>Iron deficiency based on the iron body model is calculated from the log ratio of transferrin receptor to ferritin using NHANES 2003-2006 data. Iron deficiency based on the ferritin model is calculated using 2 out of 3 cutoffs of iron deficiency variables (transferrin saturation, serum ferritin, and erythrocyte protoporphyrin, NHANES 1999-2002) (Refs. 155 and 159). Anemia was based upon iron deficiency criteria (ferritin model) and a low hemoglobin level.

<sup>6</sup>We did not receive any comments for these nutrients (for which voluntary declaration is permitted) in response to the ANPRM. In addition, dietary intake and/or biomarker data were not provided in NHANES database for chromium, biotin, iodine, pantothenic acid, molybdenum, manganese and chloride and, therefore, these nutrients are not listed in this table.

<sup>7</sup>For nutrients with an AI, prevalence of nutrient adequacy was determined when usual nutrient intakes are at or above the AI.

### L. Dietary Supplements

FDA regulations specific to dietary supplement nutrition labeling appear in § 101.36.

Many requirements in § 101.36 are consistent with the requirements for the nutrition labeling of conventional foods in § 101.9 and there are references throughout § 101.36 to requirements established in § 101.9. As discussed previously, we are proposing several amendments to § 101.9 that, if finalized, would result in significant changes to the content and format of the Nutrition Facts label. For consistency, we are proposing to amend § 101.36 so that the content and format of the Supplement Facts label corresponds with that of the Nutrition Facts label. The IOM Labeling Report included a recommendation that the Supplement Facts label should use the same DVs as the Nutrition Facts label. In light of the IOM recommendation, we requested comment in the 2007 ANPRM on whether the Supplement Facts label should use the same DVs

as the Nutrition Facts label, as suggested in the IOM labeling report. We received no comments in response to this question. We also did not receive any other comments to the 2007 ANPRM that are relevant to the Supplement Facts label.

We expect that the proposed DVs for infants 6 through 12 months, children 1 through 3 years, pregnant and lactating women, and individuals 4 years of age and older may result in reformulation of dietary supplement products. Reformulations could impact intakes of vitamins and minerals for all age groups. We invite comment, including the submission of data and other factual information, on the reformulation of dietary supplement products that may result from proposed changes to the DVs, as well as information on the potential consequences of such reformulations.

Our proposed changes to the Supplement Facts label in light of proposed changes to the Nutrition Facts label are described in this document.

#### 1. Mandatory Dietary Ingredients

In § 101.36(b)(2), we established a list of dietary ingredients that have an RDI or a DRV as established in § 101.9(c)(8)(ii) that are referred to as the "(b)(2)-dietary ingredients." These 15 nutrients must be listed in the Supplement Facts label for a dietary supplement when they are present in amounts that exceed the amount that can be declared as zero in the nutrition labeling of foods in accordance with § 101.9(c).

Section § 101.9(c)(8)(ii) requires vitamin A, vitamin C, calcium, and iron to be declared on food labels. As discussed in section II.H., we are proposing to amend § 101.9(c)(8)(ii) to allow for voluntary declaration of vitamins A and C and to require mandatory declaration of calcium, vitamin D, potassium, and iron. In addition, we are proposing to eliminate the mandatory declaration of "Calories from fat" on the Nutrition Facts label (see section II.A.1.).

We are proposing to update the list of (b)(2)-dietary ingredients to maintain consistency with the proposed requirements for nutrition labeling of foods in § 101.9. Therefore, proposed § 101.36(b)(2)(i) would: (1) No longer require declaration of vitamin A, vitamin C, or Calories from fat; (2) require vitamin D and potassium; (3) require the declaration of added sugars; and (4) retain the other (b)(2)-dietary ingredients as mandatory declarations. We are also proposing to amend § 101.36(b)(2)(i), (b)(2)(i)(B)(1), and (b)(2)(iii)(G) to remove the requirement for declaration of "Calories from fat."

## 2. Folate and Folic Acid

We are proposing to only allow the use of the term "folic acid" for the labeling of dietary supplements. Folate is a nutrient found in conventional foods, whereas folic acid is the synthetic form of folate that is added to fortified conventional foods and dietary supplements. As discussed in section II.J.2., "folic acid" or "folacin" are identified as synonyms of folate and can be used on the Nutrition Facts label (§ 101.9(c)(8)(v)) or in the Supplement Facts label (§ 101.36(b)(2)(i)(B)(2)). However, because of the difference in bioavailability between naturally occurring folate, and synthetic folic acid, we are proposing to amend § 101.9(c)(8)(v) such that the term "folate" would be used in the labeling of conventional foods that contain either folate alone or a mixture of folate and folic acid. As discussed in section II.J.2.c., we consider only the term "folic acid" to be appropriate for use in the labeling of dietary supplements. Therefore, we are proposing to amend §§ 101.36 (b)(2)(i)(B) and (b)(2)(i)(B)(2) to specify that "folic acid" is the term used to declare folic acid content of dietary supplements; and to remove "folate" and "folacin" from the list of synonyms that may be used to declare folic acid on the Supplement Facts label.

## 3. Units of Measure

In section II.J.3., we are proposing to amend § 101.9(c)(8)(iv) to replace "IU" for the RDIs for vitamin A, vitamin D, and vitamin E with mcg RAE for vitamin A, mcg for vitamin D, and mg  $\alpha$ -tocopherol for vitamin E. In addition, in section II.J.2., we are proposing to quantify and declare folate and folic acid in "mcg DFE" instead of "mcg." In the interest of maintaining consistency in nutrition labeling of foods and dietary supplements, we are proposing to amend § 101.36(b)(2)(i)(B)(3) to require that when  $\beta$ -carotene is included in parentheses following the percent statement for vitamin A, it should be declared using "mcg" (representing mcg RAE) as the unit of measure. In addition, under § 101.36(b)(2)(ii)(B), the proposed units of measure for vitamin D, vitamin E, and folate in § 101.9(c)(8)(iv) would be used in the declaration of vitamin D, vitamin E, and folic acid in the Supplement Facts label

In 2005, we received a citizen petition (Docket No. FDA-2005-P-0126 (formerly Docket No. 2005P-0293)) requesting us to preclude the declaration of  $\beta$ -carotene in supplements as vitamin A (<http://www.regulations.gov/#!docketDetail;D=FDA-2005-P-0126>). The petition maintained that the declaration of vitamin A on dietary supplement labels is misleading when the supplement contains mostly  $\beta$ -carotene because only a small amount of  $\beta$ -carotene is converted by the liver into vitamin A. We do not see a need to preclude the declaration of  $\beta$ -carotene as vitamin A, because the difference in the bioconversion of  $\beta$ -carotene to vitamin A will be accounted for with the proposed declaration of vitamin A content as "mcg" (representing mcg RAE) (see section II.J.3.). Therefore, we are not proposing to preclude the declaration of  $\beta$ -carotene in dietary supplements as vitamin A.

#### 4. Order of Nutrients Declared on the Label

For dietary supplements, § 101.36(b)(2)(i)(B) specifies that vitamins and minerals must be declared in a specific order on the Supplement Facts label. We are now proposing to establish

an RDI for choline in section I.7. Therefore, it is necessary to add choline to the list of ordered nutrients in § 101.36(b)(2)(i)(B). We are proposing to require that, when declared, choline shall follow potassium on the label.

## 5. Subpopulations

We discussed several changes in section II.K. that will affect dietary supplement labeling currently required for infants, children under 4 years of age, and pregnant and lactating women. To maintain consistency with the proposed requirements for nutrition labeling of foods in § 101.9, we tentatively conclude that it is appropriate to revise the appropriate sections of § 101.36 that pertain to labeling requirements for foods, other than infant formula, that are represented or purported to be specifically for infants 7 through 12 months, children 1 through 3 years, and pregnant and lactating women. Therefore, we are proposing to amend § 101.36(b)(2)(iii) to read as follows: "The percent of the Daily Value of all dietary ingredients declared under paragraph (b)(2)(i) of this section shall be listed, except that the percent DV for protein may be omitted as provided in § 101.9(c)(7); no percent DV shall be given for subcomponents for which DRVs have not been established (e.g., sugars)."

When the percent DV is declared for total fat, saturated fat, total carbohydrate, dietary fiber, or protein, we require that a symbol be placed next to the percent DV declaration for these nutrients that refers the consumer to a statement at the bottom of the label that says "Percent Daily Values are based on a 2,000 calorie diet." This statement is only accurate for products meant for children and adults that are 4 years of age and older. The proposed DRVs for total fat, total carbohydrate, dietary fiber, and protein for children 1 through 3 years of age are based on a 1,000 calorie diet. Therefore, when a product that is represented or purported to be for children 1 through 3 years of age contains a percent DV declaration for total fat, total carbohydrate, dietary

fiber, or protein, we are proposing to require in § 101.36(b)(2)(iii)(D) that a symbol be placed next to the percent DV declaration that refers the consumer to a statement at the bottom of the label that says "Percent Daily Values are based on a 1,000 calorie diet."

In addition, we are proposing to amend § 101.36(b)(2)(iii)(E) to change the categories of infants and children less than 4 years of age to infants 7 through 12 months of age and children 1 through 3 years of age.

Finally, because we are proposing DRVs for various nutrients for infants 7 through 12 months, children 1 through 3 years, and pregnant and lactating women (see section II.K.), we are proposing to amend § 101.36(b)(2)(iii)(F) such that the requirement for an asterisk noting that a DV has not been established would be applicable to foods for these subpopulations only when a DRV has not been established for a nutrient (i.e., for saturated fat, cholesterol, or dietary fiber for dietary supplements that are represented or purported to be for use by infants 7 through 12 months). Proposed § 101.36(b)(2)(iii)(F) states: "For declared subcomponents that have no DRVs, a symbol (e.g., an asterisk) shall be placed in the "Percent Daily Value" column that shall refer to the same symbol that is placed at the bottom of the nutrition label, below the last heavy bar and inside the box, and followed by the statement "Daily Value not established."

#### 6. Footnote

As discussed in section II.M, we are proposing to modify the footnote on the Nutrition Facts label. We are planning to conduct consumer studies related to the footnote on the Nutrition Facts label. The current footnote statement required for the Supplement Facts label differs from that which is currently required on the Nutrition Facts label. We expect that consumers that purchase dietary supplements would be more interested in information about the amount of specific micronutrients contained in dietary supplements and would be less focused on the

caloric reference value used in determining the percent DV for macronutrients. Based on the results of the consumer study, we will consider whether it is necessary to make corresponding changes to the footnote used on the Supplement Facts label when certain macronutrients are declared. We invite comment on whether we should consider changes to the footnote statement on the Supplement Facts label to be consistent with any changes to the footnote statement in the Nutrition Facts label.

#### M. Format

Nutrition information must be presented on food labels in a specific format (see e.g., § 101.9(d)-(f) and (j)). The elements of format related to the Nutrition Facts label include such features and graphic design principles as the type style (i.e., font) and size of the type (i.e., point); use of boldface, lines, and bars; arrangement of information in one or more columns; column headings; presence of a footnote and use of a symbol (such as an asterisk) to designate a footnote; and whether nutrition information is listed as a percentage or in absolute (i.e., quantitative) amounts. The elements of format also include the alignment of information; whether indentations are used in listing nutrient data; and the use of white space (or negative space) where no image or text exists. White space helps to isolate an element of the label that demands attention and provides a hierarchy and pacing of information for the reader (Ref. 160). The format may differ from package to package according to the amount of space on the package that is available for labeling, as described and detailed in the relevant sections in this document.

The format of the Nutrition Facts label was informed by a number of factors, including consumer research conducted by FDA (Refs. 161 to 163); consideration of the environment in which consumers typically use the label (i.e., grocery stores); the diversity of consumers for whom the label is intended (i.e., with respect to education, age, socioeconomic status, etc.); and

comments and data received on this issue in response to a 1990 proposed rule, as discussed in the 1993 final rule entitled Food Labeling: Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label (58 FR 2079 at 2114-2144) (the format rule). Research studies consistently confirmed that simple formats are easier to comprehend and require less consumer effort than complex information formats. A simple format is one that minimizes clutter and best meets the NLEA requirements that nutrition information should enable the public to readily observe and comprehend such information. In addition, a simple format allows consumers to search for accurate nutrition information with minimum effort, and provides information in a succinct manner that maximizes understanding.

Although the original intent of the format rule to meet the requirements and objectives of the NLEA for format has not changed, FDA is proposing certain changes to the format because of new information that has become available to us since 1993. The new information includes results of consumer research including studies that we conducted (Ref. 164), trends in health conditions (especially obesity), comments received in response to the 2005 and 2007 ANPRMs, and recommendations from FDA's Obesity Working Group (OWG) (Ref. 165). We are using this notice of proposed rulemaking to re-examine aspects of the current label format to determine which, if any, design changes may facilitate how information is conveyed to consumers.

We are not proposing an extensive reformatting of the Nutrition Facts label. The original design, which took into account fundamental design principles for communicating complex ideas with clarity, precision, and efficiency, are largely being retained (Ref. 166). Rather, our tentative views, tentative conclusions, and proposed changes include our consideration of graphic design principles such as alignment, consistency, repetition, and contrast, and place an emphasis on highlighting key nutrients and key information and removing or modifying parts of the label to

assist consumers in maintaining healthy dietary practices (Ref. 167). We consider our proposed changes to the Nutrition Facts label to be visually appealing and inviting. In general, the goal is to continue to display the information in a simple manner that is legible, readable, and follows a logical hierarchy. This presentation should serve as a visual guide to the reader that allows the eye to easily scan the label while the actual effort of reading is reduced.

Toward that end, we are proposing the following changes to the format of the Nutrition Facts label: (1) Increasing the prominence of calories and serving size; (2) reversing the order of the "Serving Size" declaration and the "Servings Per Container" declaration and increasing the prominence of "Servings Per Container"; (3) right-justifying the quantitative amounts of the serving size information; (4) changing the phrase "Amount Per Serving" to "Amount Per \_\_\_\_" with the blank filled in with the serving size; (5) removing the declaration of "Calories from fat"; (6) modifying the presentation of the "% DV" information by changing its position to the left of the name of the nutrient on certain labels, and separating it from the list of nutrients with a vertical line; (7) declaring "Added Sugars" as an indented listing directly beneath the listing for "Sugars"; (8) declaring the quantitative amounts (in addition to percent DVs) of mandatory vitamins and minerals and, when declared, voluntary vitamins and minerals; (9) requiring dual column labeling under certain conditions; (10) modifying the footnote; (11) requiring that all nutrients not currently highlighted in bold or extra bold type be highlighted in a type that is intermediate between bold or extra bold and regular (i.e., semi-bold) type; (12) adding a horizontal line directly beneath the "Nutrition Facts" heading; and (13) replacing the listing of "Total Carbohydrate" with "Total Carbs" We discuss each of these proposed amendments in this document. In addition, we are requesting comments on other issues related to the Nutrition Facts

label format, including the use of an alternative format design or requiring the use of a specific font.

Although the discussion in this document focuses primarily on the format of the standard Nutrition Facts label illustrated in § 101.9(d)(12), we also discuss certain modifications that we are proposing to be applied to other label formats to maintain consistency with the new format of the standard Nutrition Facts label. These other modifications pertain to formats for packages of products that contain two or more separately packaged foods that are intended to be eaten individually (e.g., variety packs of cereals and snacks) or that are used interchangeably for the same type of foods (e.g., round ice cream containers (§ 101.9(d)(13)); formats that apply to subpopulations (§ 101.9(e) and § 101.9(j)(5)); the simplified format (§ 101.9(f)); the tabular display on packages that do not have sufficient continuous vertical space (§ 101.9(d)(11)(iii)); and the tabular display (§ 101.9(j)(13)(ii)(A)(1)) and linear display (§ 101.9(j)(13)(ii)(A)(2)) for small packages.

#### 1. Increasing the Prominence of Calories and Serving Size

The ability to determine the caloric content of packaged foods is important for all consumers, especially those who are trying to control their total caloric intake and manage their weight. Inasmuch as overweight and obesity are major public health problems in the United States and are fundamentally a direct result of calorie consumption exceeding energy expenditure, we are interested in increasing consumer attention to the calorie content of packaged foods.

Current FDA regulations require "Calories" to be declared in a type size no smaller than 8 point (§ 101.9(d)(1)(iii)) and highlighted in bold or extra bold type or other highlighting (§ 101.9(d)(1)(iv)). While calorie information is mandatory on the Nutrition Facts label, it is

possible that modifying the Nutrition Facts label to give more prominence to calories may benefit consumers in weight control and maintenance, as noted by the OWG in its final report entitled "Calories Count" (Ref. 165).

The OWG recommended, in part, that FDA issue an ANPRM to solicit comments on how to give more prominence to calories on the food label. The OWG suggested possible changes to the Nutrition Facts label, such as increasing the prominence of "Calories" and "Serving Size," providing a percent DV for calories, and eliminating the "Calories from fat" declaration, which may detract from the emphasis on total calories. The OWG recommended that we obtain information on the effectiveness of these options on consumer understanding and behavior related to calorie intake (Ref. 165). After issuing the 2005 ANPRM, in which we solicited comment on the OWG recommendations, we received several comments that generally supported increasing the prominence of calories on the Nutrition Facts label. These comments suggested various approaches for doing so, and pointed out the need for additional research to fully understand the effects of potential label changes on consumer understanding and behavior (Ref. 47).

We considered available data from consumer research and comments received in response to the ANPRMs. Research conducted for warning labels and drug label formats has consistently demonstrated that increasing type size, among other things, increases attention to, and improves understanding of warning information, especially for older consumers and those with limited vision (Refs. 168 to 170). Also, our research on food labels with two servings per container found that labeling changes that highlighted the number of servings per container (via text or a dual column) served as cues to consumers that the product contained more than one

serving and helped them more accurately determine the number of calories per container (Ref. 164).

We tentatively conclude that the proposed changes to the number of calories per serving and the number of servings per container would result in these declarations serving as an anchor to the Nutrition Facts label by focusing the reader's attention to this information and therefore would assist consumers to effectively use this information in the Nutrition Facts label (Ref. 171). Accordingly, we are proposing to revise § 101.9(d) to increase the type size for "Calories" and the numeric value for "Calories." We are also proposing that the numeric value for calories be highlighted in bold or extra bold type in order to draw attention to this information, emphasize the importance of calories on the label, and maintain consistency with the bolded declaration for "Calories." We invite comment on these tentative conclusions.

We also consider it appropriate to make corresponding changes to the prominence of calories on the Supplement Facts label, when "Calories" is declared. Although the majority of dietary supplement products contain a negligible amount of calories, and therefore calories are not declared on most Supplement Facts labels, we note that some dietary supplement products may contain a significant amount of calories and macronutrients. We are concerned that a small number of dietary supplement products, especially those in liquid form, could contribute a significant amount of calories and other macronutrients to the diet when consumed regularly. For such products, our tentative view is that it may be necessary for the Supplement Facts label to have a format similar to the format being proposed for the Nutrition Facts label with respect to increasing the prominence of information for calories. We invite comment on whether any of the changes that are being proposed to the Nutrition Facts label in the following sections should also be required for certain products with Supplement Facts labels that list calories and/or other

macronutrients, and if so, under what conditions and for which dietary supplement products should such labeling be required.

## 2. Changing the Order of the "Serving Size" and "Servings Per Container" Declarations and Increasing the Prominence of "Servings Per Container"

Current regulations specify that information on serving size, consisting of a statement of the serving size (§ 101.9(d)(3)(i)) and the number of servings per container (§ 101.9(d)(3)(ii)), shall immediately follow the identifying heading of "Nutrition Facts." In addition, "Serving Size" and "Servings Per Container" must be in a type size no smaller than 8 point (§ 101.9(d)(1)(iii)). As mentioned previously, we are interested in taking steps to increase consumer attention to the calorie content in packaged foods, such as by increasing the prominence of this information as suggested by the OWG. Consumer research on information displays suggests that accuracy of judgments and quality of decisions are improved when information displays closely match the judgment and decision needs of consumers (Refs. 172 and 173). With respect to the Nutrition Facts label, an important consumer need is to identify the number of servings per container of a packaged food. Therefore, placing "Servings Per Container" above "Serving Size" would be expected to help consumers find the number of servings per container with less effort than is now needed. Listing "\_\_\_ servings per container" with the blank filled in with the actual number of servings directly beneath the "Nutrition Facts" heading, and highlighting it in bold or extra bold type would also help increase awareness that the information presented in the Nutrition Facts label does not refer to the contents of the entire package when the label indicates that there is more than one serving per container. Further, listing "Serving size" in the same proximity to where the actual nutrient information is located on the label would help consumers understand that this nutrient information pertains to the

particular serving size that is declared. Proximity is a graphic design principle that asserts that items closer together are perceived to be more related (Ref. 167) This, in turn, would help consumers grasp the relative significance of a particular food product in the context of their daily diet.

Therefore, based on the available data and information discussed previously, including graphic design principle, of proximity we tentatively conclude that reversing the order of the declarations of "Servings Per Container" and "Serving Size" would help consumers more readily observe and comprehend the nutrition information appearing in the Nutrition Facts label, allow consumers to search for information with a minimum of effort, and assist consumers in their food purchasing decisions and in maintaining healthy dietary practices. Accordingly, we are proposing to re-designate § 101.9(d)(3)(i) as § 101.9(d)(3)(ii), re-designate § 101.9(d)(3)(ii) as § 101.9(d)(3)(i), and make changes in how the serving size information is capitalized on the label so that no capital letters are used, except for the first letter in "Serving size." (Current § 101.9(d)(3)(i) and (d)(3)(ii) specify that information on serving size be capitalized and listed as "Serving Size" and "Servings Per Container.") We also are proposing to require that the declaration of "\_\_\_ servings per container" (with the blank filled in with the actual number of servings) be highlighted in bold or extra bold type, and be in a type size no smaller than 11 point (except for the tabular and linear displays for small packages) (proposed § 101.9(d)(3)(i)) and that the serving size information must be in a type size no smaller than 8 point (except for the linear display for small packages) (proposed § 101.9(d)(3)(ii)). We tentatively conclude that these proposed changes would lessen the effort of consumers to locate this information, and assist them in accurately identifying the calorie amounts and nutrient contents of packaged food products.

Current regulations regarding serving size information for dietary supplements is described in § 101.36(b)(1). When taking dietary supplements, consumers need to know how much of the product to take (e.g., 1 capsule, 2 tablets, 1 packet). This information, which is currently provided in the "Serving Size" line of the Supplement Facts label, is more important for the consumer to know than the number of servings (e.g., 100 tablets) contained in the package. We received no comments recommending that the serving size or servings per container information on the Supplement Facts label should be made more prominent or noticeable. Therefore, our tentative conclusion is that there is no need to propose changing the order of how serving size and servings per container are listed on the Supplement Facts label, or to make amendments in the type size or capitalization corresponding to our proposed changes for this information on the Nutrition Facts labels. We invite comment on these tentative conclusions.

### 3. Right-Justifying the Quantitative Amounts Declared in the "Serving size" Statement

We have also tentatively concluded, based on design considerations, that the label statement for "Serving size" in both household unit (§ 101.9(b)(5), refers to a common household measure such as a cup, tablespoon, piece or slice) and gram amounts must be right-justified on the same line that "Serving size" is listed. Currently, this numerical information is stated immediately adjacent to the "Serving Size" declaration, as seen in current § 101.9(d)(12). By keeping the proposed "Serving size" declaration left-justified while right-justifying the corresponding numerical values, the proposed change would create white space on the Nutrition Facts label that would result in a less cluttered appearance, heightened focus and emphasis, and improved readability (Ref. 160). This design feature would provide enhanced emphasis to the information about serving size, allowing this information to be more noticeable and thereby facilitating its access and use by consumers. We invite comment on this tentative conclusion.

#### 4. Changing the "Amount Per Serving" Statement

Current regulations specify that the Nutrition Facts label shall include a subheading designated as "Amount Per Serving" and that this subheading shall be separated from the serving size information by a bar (§ 101.9(d)(4)) and be highlighted in bold or extra bold type or other highlighting (§ 109(d)(1)(iv)). We are proposing, based in part on the consumer research previously cited (Refs. 172 and 173), to change the "Amount Per Serving" declaration to "Amount per \_\_\_" with the blank filled in with the actual serving size expressed in household units, and to increase the type size. These changes would make it easier for label users to judge the amounts of nutrients per serving because it removes the need for label users to refer back to the unit of the serving size which is currently declared just below the Nutrition Facts heading and which would be declared under the number of servings per container in the proposed label formats.

Other studies suggest that consumers are often confused by serving size information as it is currently presented on the Nutrition Facts label (Refs. 174 and 175). Therefore, specifying the actual serving size in the listing of "Amount per \_\_\_" declaration would be expected to help consumers more readily observe and comprehend the nutrition information appearing in the label. Based on the reasons provided, we tentatively conclude that changing the "Amount Per Serving" statement to "Amount per \_\_\_" with the blank filled in with the actual serving size and increasing the type size would assist consumers in using the information and may lessen the time and effort needed to locate the target information. Accordingly, we are proposing to amend § 101.9(d)(4) by requiring that the Nutrition Facts label specify what the serving size actually is by declaring "Amount per \_\_\_" with the blank filled in with the actual serving size in household units as indicated in the "Serving size" declaration. To further facilitate use of the Nutrition

Facts label, as mentioned in section 2, we are proposing to move the "Serving size" declaration closer to the proposed "Amount per \_\_\_\_" listing. We also are proposing to require that the "Amount per \_\_\_\_" information be highlighted in semi-bold, rather than in bold or extra bold, in order not to detract from the calories information. In addition, we are proposing that the type size of the "Amount per \_\_\_\_" declaration be no smaller than 8 point (except for the linear display for small packages). We invite comment on our tentative conclusions.

#### 5. Declaration of "Calories from Fat"

We have tentatively concluded that a declaration of calories from fat on the Nutrition Facts label is not necessary to assist consumers in maintaining healthy dietary practices and, consequently, we are proposing to remove the current requirement for declaration of "Calories from fat" (see section II.A.1.). Our Consumer research (Ref. 164), which evaluated a label format that did not contain the "Calories from fat" statement, found that the lack of this information had no effect on consumers' judgments of product healthfulness, accuracy in identifying nutrient contents of products, or perceptions of the label. These findings support our proposal to remove the "Calories from fat" declaration from the Nutrition Facts label.

#### 6. Presentation of Percent DVs

The format for listing nutrients with DRVs on the Nutrition Facts label, including the quantitative amount by weight and percent DVs, is described in § 101.9(d)(7). In establishing the requirements for percent DV declaration, we considered that this information would help consumers evaluate the nutrient characteristics of a single product (e.g., how high or low a particular product is in certain nutrients or the extent to which it contributes toward daily nutritional goals) and assist them in making choices between products (58 FR 2079 at 2121). Consumer research at that time of rulemaking for the Nutrition Facts label (Ref. 162) indicated

that the percent DV information improved consumers' abilities to make correct dietary judgments about a food in the context of a total daily diet. Research also indicated that percent DV information helped consumers to verify the accuracy of front-panel claims (Ref. 163). We received comments on the format of the Nutrition Facts label in response to the 2007 ANPRM (Ref. 47) that suggested modifying the way percent DV is presented to facilitate greater use of this information, although one comment suggested that the percent DV should not be used on the label. Other comments noted the need for additional consumer research and a comprehensive consumer education program.

We continue to believe that the percent DV information on the Nutrition Facts label can serve a number of useful purposes, including helping consumers to compare foods; determine if a serving of food is high or low in a particular nutrient; and make dietary trade-offs among food choices throughout the day. As such, we do not agree that the percent DV declarations should be eliminated from the Nutrition Facts label. We are proposing to switch using the "% Daily Value" to the "% DV" in the column that is above the nutrient listings. The "% DV" is used on some of nutrition facts labels for smaller packages and we think this will help with maintaining consistency among the labels. In addition we are adding a hairline rule (see discussion in this document) to differentiate the DVs from the nutrients and using "% DV" as the header which maintains the alignment of the heading over the DV column. Therefore based on the graphic design principle of alignment (Ref. 167) and in order to promote consistency of the labels we tentatively conclude to use "% DV" as the column header over the numerical listing of the nutrients DVs (proposed § 101.9(d)(7)(ii)).

We have considered alternative terms that may be more readily understandable than Daily Value, such as Daily Guide or Daily Need, and invite comment on these or other terms.

The issue of using an appropriate single term to refer to all of the reference values in the nutrition label was previously discussed in the format rule (58 FR 2079 at 2124), in which we explained our rationale for deciding upon the single term "Daily Value." We also request comment on whether the word "percent" (or the % symbol) should precede whatever term is used in the column heading where the percent DVs are listed, as specified in current § 101.9(d)(6). Since the % symbol is currently included next to the numerical values that are listed in this column, including the word "percent" or the % symbol in the column heading may be redundant and, after considering comments, we may remove that requirement in a final rule. For the reasons explained previously, we are not proposing to change the requirements for the declaration of percent DV for all nutrients, as specified in § 101.9(c)(8) and § 101.9(d)(7).

As discussed previously, percent DV is intended to help consumers make dietary decisions. Therefore, we tentatively conclude that making the percent DV more prominent may make the information even more useful to consumers than it is now. One potential approach to making the percent DV more prominent is to rearrange the positions of the columns listing the percent DV information. As currently described in § 101.9(d)(6), and § 101.9(d)(7) the percent should be arranged on the right of certain Nutrition Facts label formats. For labels displaying the tabular format (proposed § 101.9(d)(11)(iii)), the standard format (proposed § 101.9(d)(12)), the format for infants 7 to 12 months of age (proposed § 101.9(j)(5)(i)), the tabular format for small packages, (proposed § 101.9(j)(13)(ii)(A)(1)), the linear display (proposed § 101.9(j)(13)(ii)(A)(2)), and the simplified format (as described in current § 101.9(f)), we propose to list percent DVs in a column to the left of the names of the nutrients and their quantitative amounts, with a thin vertical line separating the "% DV" column from the list of nutrients.

The rearrangement is based on the graphic design principles of primacy (which asserts that initial items in a list are stored more efficiently in memory than items listed later), proximity (which asserts that elements positioned close together are perceived as a single group), and the importance of white space (which, among other things, is used by designers to isolate an element that demands attention) (Ref. 160 and 167), and the fact that English text is read from left to right. The addition of a vertical hairline rule to the right of the "% DV" column assists in chunking this information, thereby accentuating it and further distinguishing it from the nutrient name and the quantitative weight information. Chunking is a technique for combining multiple units of information into a limited number of units or chunks so that the information is easier to process and remember) (Ref. 167). Based on these design principles, positioning the % DV to the left of the label should increase consumers focus on the % DV. Displaying the % DV in this manner would assist consumers in understanding the relevant contribution of a nutrient in a food to the diet by highlighting the % DV information on the label more than on the current label format (where % DV is listed on the right of the label).

We tentatively conclude that the proposed rearrangement would assist consumers by helping them to understand the nutrition information on the label in the context of a total daily diet. We are unaware of any consumer survey data concerning this particular proposed change related to consumer understanding and use of the information. Although, we are aware that the prevalence of inadequate numeracy (defined as "the ability to comprehend, use, and attach meaning to numbers" (Ref. 176) and low literacy in the population have been persistent concerns regarding the ability of consumers to comprehend health-related information, it is unclear to what extent the changes we are proposing to the positioning of the % DV from its current placement would have on overall consumer use or understanding. We are also aware that the

prominence of the percent DV first could potentially make the Nutrition Facts label appear less user-friendly particularly to frequent users of Nutrition Facts labels, who have grown accustomed to the format and organization of the existing Nutrition Facts label. In addition, we acknowledge that moving the % DVs to the left could potentially draw consumer attention from nutrients that do not have a DV. We invite comment and data on the tentative conclusion to shift the "% DV" to the left of the Nutrition Facts label.

On all dual column labels, including those (1) for two or more forms of the same food (proposed § 101.9(e)(5)); (2) displaying nutrition information per container and per unit, in addition to nutrition information per serving (proposed § 101.9(e)(6)(i)); (3) using the tabular display (proposed § 101.9(e)(6)(ii)), and; (4) that provide the aggregate display (proposed § 101.9(d)(13)(ii)), we propose to list the names of nutrients on the right side of the % DV column, followed by the quantitative (weight) amounts of each nutrient. In each of these labels, we propose to use thin vertical lines to separate the information in the "% DV" column from the information in the column containing the quantitative weights. Further, we propose to use the same style of thin vertical lines to separate each of the dual columns and aggregate display columns from each other. The use of these vertical lines helps to differentiate the columns and make the information easier for consumers to read and identify (Ref. 167). We invite comment on this tentative conclusion.

As described in the Dietary Supplement Health and Education Act of 1994, dietary supplements are products taken by mouth containing "dietary ingredients" that are intended to supplement the diet. They may contain not only vitamins and minerals, but also herbs or other botanicals and amino acids, as well as concentrates, metabolites, constituents, and extracts of these dietary ingredients (section 201(ff) of the FD&C Act). Thus, many dietary supplement

products contain few or no dietary ingredients with DRVs or RDIs, and therefore would not list any percent DVs on the Supplement Facts label. Further, consumers taking dietary supplements may find information about the quantitative amounts of dietary ingredients in the product to be of equal or greater importance than a percent DV listing, even if a DV existed for an ingredient contained in the dietary supplement. Therefore, we are not proposing any changes in the position of the percent DV listing on the Supplement Facts label relative to the position of the nutrient and dietary ingredient information. As mentioned previously, we are proposing to require that the Nutrition Facts labels that include dual columns contain vertical lines separating the percent DV information from the quantitative amounts per weight listings in each of the dual columns, and to separate the dual columns from each other. We invite comment on whether there is a need to include vertical lines that are similarly placed on Supplement Facts labels for multiple vitamins in packets (§ 101.36(e)(11)(iii)) and for dietary supplements that list "per serving" and "per day" information (§ 101.36(e)(11)(viii)).

Current § 101.9(j)(5)(ii)(A), (j)(5)(ii)(C), and (j)(5)(ii)(D) include certain provisions for the presentation of percent DV for nutrients on the Nutrition Facts label of foods represented or purported to be specifically for infants and children less than 4 years of age. In particular, the percent DVs for protein, vitamins, and minerals are listed in a separate section of the Nutrition Facts label below the quantitative information by weight for protein. As discussed in section II.K., we are proposing changes to the nutrition labeling of foods represented or purported to be specifically for infants 7 through 12 months, children 1 through 3 years of age, and pregnant and lactating women. These include, among other things: (1) Establishing RDIs and DRVs that are used in determining the percent DVs declared on the label; and (2) allowing for certain percent DV declarations that are currently excluded in § 101.9(j)(5)(ii)(A). Given these proposed

amendments that would require percent DV declarations for macronutrients, we invite comment on the appropriate placement of percent DVs in the labeling of foods for infants 7 through 12 months, children 1 through 3 years of age, and pregnant and lactating women. We are considering listing the percent DV to the left of the name of any nutrient that has a DV, as shown in proposed § 101.9(j)(5)(i), similar to the placement of the declaration of percent DVs in the labeling of foods for the general population. Therefore, we are proposing that the percent DV for protein would no longer be listed with the vitamins and minerals at the bottom of the label as currently required.

#### 7. Placement of "Added Sugars"

As discussed in section II.D.3., we are proposing to require the declaration of added sugars as an indented line item underneath the declaration of total sugars on the Nutrition Facts label. If finalized, added sugars would be the first mandatory nutrient required to be listed in a double indentation format on the Nutrition Facts label. FDA regulations permit the voluntary declaration of "soluble fiber" and "insoluble fiber" as double indented listings under "dietary fiber" (§ 101.9(c)(6)(i)). We are planning to conduct a consumer study (78 FR 32394, May 30, 2013) that will include, among other things, questions regarding the declaration of added sugars on the Nutrition Facts label. The results of this study will help enhance our understanding of how consumers would comprehend and use this new information. We will publish the results of the study when they become available. We are interested in receiving, as part of any comment, other available research data and other factual information relevant to this issue, including the proposed double indented placement of added sugars below total sugars.

#### 8. Declaration of Absolute Amounts of Vitamins and Minerals

A declaration of the quantitative amount by weight is required for both mandatory and voluntary nutrients that are declared on the Nutrition Facts label, except for vitamins and minerals (other than sodium and potassium) which must be declared only as percent DVs. As discussed in section II.I.6., we are proposing to require the declaration of the absolute amounts for all mandatory and voluntary vitamins and minerals, in addition to the requirement for percent DV declaration. An exception to this proposed requirement would be Nutrition Facts labels for foods in small packages that have a total surface area available to bear labeling of 40 or less square inches. Because of space limitations, we are not proposing any changes to the tabular display (§ 101.9(j)(13)(ii)(A)(1)) and the linear display (§ 101.9(j)(13)(ii)(A)(2)) on packages that have a total surface area available to bear labeling of 40 or less square inches, where vitamins and minerals (other than sodium) would have to be declared only as percent DVs.

#### 9. Single and Dual Column Labeling

There are currently multiple provisions for voluntary dual column labeling. For example, there is dual column labeling that presents nutrition information per serving size and per 100 g or 100 mL, or per 1oz or 1fl oz. of the food as packaged or purchased (§ 101.9(b)(10)(i)). Dual column labeling is mandatory for products that are promoted on the label, or in advertising, for a use that differs in quantity by twofold or greater from the use upon which the reference amount was based (e.g., liquid cream substitutes promoted for use with breakfast cereals) (§ 101.9(b)(11)). We are also proposing for foods that are commonly combined with other ingredients or that are cooked otherwise prepared before eating to present the percent DVs and the quantitative amounts for both the food in the "as purchased" form and for the "as prepared" form in § 101.9(h)(4).

We are proposing under certain conditions (i.e., when the package contains at least 200 percent and up to and including 400 percent of the applicable reference amount customarily consumed) to require dual column labeling where nutrition information would be presented based both on the serving size and on the entire package or unit of food. This is described in a proposed rule entitled "Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments" (serving size proposed rule) that is published elsewhere in this issue of the Federal Register.

In addition to proposing dual-column labeling per serving and per container (or unit, as applicable) for all nutrition information on the label, we are considering two additional options that would require nutrition information per serving and per container for only certain declarations but not all label declarations for containers of food or units of food, as applicable, containing at least 200 percent and up to and including 400 percent of the applicable RACC. The first option is for a label that includes calorie information per serving and per container (or unit, as applicable) following the serving size information in the Nutrition Facts label. With this option, the remaining nutrition information would be listed on a per serving basis only and in a single column below the calorie information per serving and per container. The second option is to provide nutrition information per serving and per container (or unit, as applicable) for calories, saturated fat and sodium following the serving size information in the Nutrition Facts label and the remaining nutrition information would be listed on a per serving basis in a single column below the dual column provided for calories, saturated fat and sodium declarations. These options may specifically highlight the calorie content alone, and the calorie content, saturated fat

content, and sodium content, respectively, for both the serving size and the entire container of food (or unit, as applicable). These options would focus on a smaller number of nutrients presented per serving and per container of food (or unit, applicable) that the U.S. population should limit for those foods with at least 200 percent and up to and including 400 percent of the RACC. We question whether consumers would be more inclined to use dual column labeling for a smaller set of nutrients. We invite comment and data on dual column labeling as proposed in this rule as well as the options presented for providing nutrition information per serving and per container (or unit, as applicable) for only certain declarations.

We will consider whether to require one of these options in the serving size final rule after considering comments on the serving size proposed rule.

#### 10. The Footnote

The Nutrition Facts label requires an asterisk following the "% Daily Value" declaration that refers to a footnote statement that reads: "\*Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values may be higher or lower depending on your calorie needs" (§ 101.9(d)(9)(i)). Below this footnote, a table that lists DRVs for total fat, saturated fat, cholesterol, sodium, total carbohydrate, and dietary fiber based on 2,000 and 2,500 calorie diets must be provided (§ 101.9(d)(9)(i)). This table was originally included in the Nutrition Facts label to assist consumers in estimating their own quantitative dietary needs relative to the reference DVs (58 FR 2079 at 2127). It was also intended to communicate that some DVs vary with caloric intake whereas others do not. Specifically, only the DRVs for the macronutrients (i.e., total fat, saturated fat, total carbohydrate, dietary fiber, and protein) differ according to calorie needs while the current DRVs for cholesterol, sodium, and potassium, as well as the RDIs for essential vitamins and minerals, do not vary according to caloric intake, and therefore are the

same for both the 2,000 and 2,500 calorie levels listed in the footnote. Finally, a statement indicating that the kcal/g for fat, carbohydrate, and protein are 9, 4, and 4, respectively, is permitted to be declared below the DRVs table (§ 101.9(d)(10)).

Several comments to the 2007 ANPRM suggested deleting either the entire footnote or the DRVs table from the footnote, and stated that the footnote information is not readily useable or understood by consumers and may be potentially confusing. Other comments recommended replacing the footnote with a short, simple statement that directs consumers to the USDA's MyPyramid Web site (which has now been replaced with ChooseMyPlate.gov) for further information. We do not agree with these latter comments, as information on the Nutrition Facts label should be available to the consumer at the time of product purchase or consumption.

The percent DV is not described in the footnote or anywhere else on the Nutrition Facts label and we are interested in whether such a description would help improve consumer understanding of the percent DV information. In addition, as one comment pointed out, a recent study by the International Food Information Council Foundation entitled "Food Label and Consumer Research Project" showed that some consumers did not understand what was being conveyed in the percent DV explanatory footnote and others thought that the DRVs table changed according to the content of each food and beverage product. Therefore, although data indicate that the DRVs table is not well understood by consumers, it also appears unlikely that consumers would understand this information any better if calorie values were lowered or if a separate listing for men and women were provided, as was suggested by some comments. Therefore, we are proposing to remove the requirement for the footnote table listing the DRVs for total fat, saturated fat, cholesterol, sodium, total carbohydrate, and dietary fiber for 2,000 and 2,500 calorie diets that is specified in § 101.9(d)(9)(i).

We also note that consumers are better able to discriminate between more and less healthful products when they are given an explanation about percent DVs than when they are not (Ref. 177). Therefore, it is our tentative view that a new footnote statement containing informational text to help consumers interpret the meaning of the percent DV and use the DVs is needed. Such information may include a definition of the percent DV, a succinct statement regarding calorie intake, and/or an explanation of when the percent DV signifies a relatively high or low level of a nutrient, such as the "5/20 rule," which we describe in this document. In addition, it is our tentative view that such a footnote statement should be simple and easy to understand, as simplified information is more useful and accessible to consumers than complex information (Ref. 178).

We also recognize that the footnote appearing in small type size at the bottom of the label may have made it less noticeable to consumers and therefore of less use than if it had been larger and otherwise more noticeable. Therefore, it is our tentative view that increasing the type size, bolding key elements of the footnote (space permitting), and adding a bar clearly separating it from the micronutrient information directly above will assist consumers in using the information. Again, we request comment on the impact such changes would have on enhancing consumers' use of the percent DV. We will consider comments we receive and whether to include such changes in the final rule.

We also consider that a succinct statement about daily calorie intake (2,000 calories) is a necessary part of the footnote because 2,000 calories is consistent with widely used food plans (76 FR 19192 at 19209), the percent DV of certain nutrients (e.g., total fat, total carbohydrate, and dietary fiber) is based on 2,000 calories, and 2,000 calories approximates the estimated energy need for adults who are sedentary to moderately active. However, we recognize that a

succinct statement about daily calorie intake should not suggest that the percent DV of all nutrients is linked to a 2,000 calorie diet.

As previously discussed in section II.M.7, we are planning to conduct consumer research on various format issues, including percent DV information in the footnote area. We agree that consumer education programs are important, and have offered such programs on our Web site to a variety of audiences, including young individuals (Ref. 179). We will consider additional efforts, as appropriate. In an effort to provide consumers with a general approach for using the percent DV to evaluate the nutrient content in foods, we have explained on our Web site that, as a general frame of reference, a 5 percent DV or less is low and a 20 percent DV or more is high (often called the "5/20 rule") (Ref. 180). Even though this general frame of reference has been publicized and advocated by the 2010 DGA (Ref. 6) and various Web sites (Ref. 181), it is unclear whether consumers are aware of the "5/20 rule," and to what extent it can improve consumer judgments about what constitutes high or low levels of nutrients in foods since quantitative information about food constituents is difficult for consumer to interpret (Ref. 180 ). The "5/20 rule" also closely approximates FDA regulations for nutrient content claims that provide criteria for the terms "low" (§§ 101.61 and 101.62) and the terms "rich in" and "excellent source" (§ 101.54). Thus, the "5/20 rule" could assist consumers in choosing foods that are high in specific nutrients they want to consume more of (e.g., calcium) and/or low in nutrients they want to eat less of (e.g., saturated fat). To inform our decision on how best to construct the new footnote, including its content and format, we plan to conduct consumer research during this rulemaking that will test consumer reactions to a definition of percent DV, a succinct statement on calories, and several statements related to the "5/20 rule" (77 FR 32120, May 31, 2012, and 78 FR 32394). We will make the results of this study available for public review and comment.

We request comments, including available data and information (such as experimental evidence) related to this issue.

We are not aware of data gathered since the NLEA's implementation on whether listing information about converting gram amounts of fat, carbohydrate, and protein to calories has been useful to consumers. We are not proposing changes to this aspect of the footnote specified in § 101.9(d)(10). However, we request comments and supporting data on whether or not this calorie conversion information should continue to be optional on the Nutrition Facts label, and whether there are any data suggesting that consumers do or do not use this information. We may consider deleting this optional requirement in the final rule if we determine the information is not useful. We will consider corresponding changes to the footnote requirements for the Supplement Facts label consistent with any changes to the footnote on the Nutrition Facts label.

#### 11. Use of Highlighting With a Type Intermediate Between Bold or Extra Bold and Regular Type

Currently, only nutrients that are not indented (i.e., "Calories," "Total Fat," "Cholesterol," "Sodium," "Total Carbohydrate," and "Protein") on the Nutrition Facts label are required to be highlighted in bold or extra bold type or other highlighting (§ 101.9(d)(1)(iv)). We have tentatively concluded, based on design considerations of highlighting information in Bold type (Ref. 167) would help differentiate the name of the nutrient from its absolute amount, that all of the other nutrients listed on the Nutrition Facts label, including those that are indented and the vitamins and minerals, should also be highlighted in order to set them apart from other information that appears in the Nutrition Facts label. The key nutrients that are not indented above would still be highlighted in a font that is bolder than the indented nutrients, so the overall style of the Nutrition Facts label will not change. Accordingly, we are proposing to amend

§ 101.9(d)(1)(iv) to remove the restriction that prohibits any other information on the label to be highlighted, and to require that all voluntary nutrients specified in § 101.9(c), including the vitamins and minerals listed in § 101.9(c)(8)(iv), appear in a type intermediate between bold and regular type (if bold type is used) or between extra bold and regular type (if extra bold type is used) on the Nutrition Facts label.

## 12. Addition of a Horizontal Line Beneath the Nutrition Facts Heading

The current label requires that the Nutrition Facts heading be set in a type size larger than all other print size in the nutrition label (§ 101.9(d)(2)) but does not require that this heading be set apart from the rest of the label with a horizontal hairline rule, which is a thin line. Horizontal lines are used throughout the Nutrition Facts label as a key graphic element to divide space, direct the eye, and give the label a unique and identifiable look. The repeated use of horizontal lines helps develop the organization of the label, strengthens the label's unity, accentuates width, and promotes stability (Ref. 182). The addition of a hairline rule immediately below the Nutrition Facts heading directs the reader's eye to the serving size information, further emphasizes the information about servings, and helps break the information into small chunks, thus making it easier to process and remember the information (Ref. 167). Accordingly, we have tentatively concluded that a 0.25 point hairline rule shall be inserted directly beneath the Nutrition Fact heading on all label formats, with the exception of the linear display for small packages. We invite comment on this tentative conclusion.

## 13. Replacing "Total Carbohydrate" With "Total Carbs"

Nutrition information declared on the Nutrition Facts label must be presented using the nutrient names specified in § 101.9(c) or § 101.9(j)(13)(ii)(B). According to § 101.9(c)(6), the nutrient name used for listing information about the carbohydrate content of a product is "Total

Carbohydrate." Certain abbreviations, as specified in § 101.9(j)(13)(ii)(B), may be used on the Nutrition Facts label on packages that have a total surface area available to bear labeling of 40 or less square inches. In addition, the term "carb" is commonly used as a shortened term or acronym for "carbohydrate" (Ref. 183). Although the current abbreviation for "Total carbohydrate" is "Total carb," we found that "total carbs" was extensively preferred over "total carb" as a Google search term during the past 15 years, suggesting that "carbs" is the more commonly used term by the general public (Ref. 184). As previously discussed, we are interested in maximizing the amount of white space on the Nutrition Facts label and in maintaining a simple format that minimizes clutter and enables the public to readily observe and comprehend the nutrition information that is presented. For the reasons set forth previously, we tentatively conclude that using the term "Total Carbs" instead of "Total Carbohydrate" would help achieve these objectives. Accordingly, we are proposing to amend § 101.9(c)(6) and § 101.9(j)(13)(ii)(B) by requiring that the total carbohydrate content in a serving be listed as "Total Carbs" instead of "Total Carbohydrate" or "Total Carb" and that this listing be used on all label formats. We invite comment on this tentative conclusion.

#### 14. Alternative Visual Formats/Fonts

We considered the utility of alternative visual presentation formats, in response to some comments that suggested using charts or graphs to facilitate consumer understanding (Ref. 47). During the development of the current label format, we examined alternative graphic designs, including graphs, and determined that the current format was optimal (Ref. 185). Since 1993, we reviewed two published studies that explored alternative graphical formats (Refs. 172 and 186). These studies provided limited and mixed evidence in support of the tested formats. For example, one study (Ref. 186) did not investigate how graphical formats would perform when

individuals have to compare the healthfulness of more than one product simultaneously. The other study (Ref. 172) demonstrated that when participants used the test labels to compare two products, the alternative graphical format was not unequivocally superior to a format resembling the standard Nutrition Facts format, and indeed the graphical display appeared to be inferior to the Nutrition Facts-type format in supporting consumers' ability to calculate the number of servings of a food that would provide the daily value of particular nutrients. Therefore, in the absence of conclusive evidence to support alternative graphical layouts, we are not proposing any changes to the basic format of the Nutrition Facts label as specified in § 101.9(d)(12).

However, we invite comment on an alternative concept for the Nutrition Facts label format that indicates "quick facts" (e.g., amount of total carbohydrate, fat and protein) about a product's nutrient content first, and then explicitly points out nutrients to "avoid too much" of as well as nutrients to "get enough" of as a way to categorize the nutrient declarations in the Nutrition Facts label. We previously considered this concept of separating nutrients out on the label and would like to reconsider it (Ref. 163). We request comment on how this display may or may not convey the information in a manner which enables the public to readily observe and comprehend such information and whether separating and placing nutrients such as "Total Fat and "Saturated Fat" under different headings would help or hinder consumer's understanding of the Nutrition Facts label. We are also interested in comments on what headings could be used and how to categorize all of the nutrients.

Additionally, we are seeking comment on whether a specific type style should be required for the Nutrition Facts label. Currently, we specify in § 101.9(d)(1)(ii)(A) that the type style should be a "single easy-to-read type style" but no specific type style is required. However, in § 101.9(d)(1) we urge that certain type styles (i.e., Helvetica Black, Helvetica Regular,

Franklin Gothic Heavy) and other graphic design features be used, as described in appendix B to title 21, part 101, of the Code of Federal Regulations. We request comment on whether a specific font should be required to ensure the readability of the Nutrition Facts label.

<b>Nutrition Facts</b>	
<b>8 servings per container</b>	
Serving size	2/3 cup (55g)
<b>Amount per 2/3 cup</b>	
<b>Calories</b>	<b>230</b>
<b>% Daily Value*</b>	
<b>QUICK FACTS:</b>	
<b>12%</b>	<b>Total Fat</b> 8g
<b>12%</b>	<b>Total Carbs</b> 37g
	Sugars 1g
	<b>Protein</b> 3g
<b>AVOID TOO MUCH:</b>	
<b>5%</b>	<b>Saturated Fat</b> 1g
	<i>Trans</i> Fat 0g
<b>0%</b>	<b>Cholesterol</b> 0mg
<b>7%</b>	<b>Sodium</b> 160mg
	Added Sugars 0g
<b>GET ENOUGH:</b>	
<b>14%</b>	<b>Fiber</b> 4g
<b>10%</b>	<b>Vitamin D</b> 2mcg
<b>20%</b>	<b>Calcium</b> 260mg
<b>45%</b>	<b>Iron</b> 8mg
<b>5%</b>	<b>Potassium</b> 235mg
* Footnote on Daily Values (DV) and calorie reference to be inserted here.	

### N. Compliance

Section 101.9(g) provides information about how we determine compliance with our nutrition labeling requirements, including the methods of analysis used to determine compliance,

reasonable excesses and deficiencies of nutrients, and acceptable levels of variance from declared values. Based on the proposed changes to other sections of § 101.9 (discussed in sections II.A. to II.M.) and taking into account comments in response to the 2007 ANPRM, we are proposing several changes to § 101.9(g), which we discuss in this document.

#### 1. Level of Variance Allowed for the Label Declaration of Specific Nutrients

Section 101.9(g)(5) establishes that a food with a label declaration of calories, sugars, total fat, saturated fat, trans fat, cholesterol, or sodium shall be deemed to be misbranded under section 403(a) of the FD&C Act if the nutrient content of the composite is greater than 20 percent in excess of the value for that nutrient declared on the label. In addition, no regulatory action will be based on a determination of a nutrient value that falls above this level by a factor less than the variability generally recognized for the analytical method used in that food at the level involved.

One comment to the 2007 ANPRM asked us to reevaluate the level of variance permitted for nutrient content declarations, particularly for added nutrients of concern such as sodium, sugar, and fat. Expressing concern that the current practice could result in the provision of inaccurate and misleading information to consumers, the comment recommended that if we are unable to reduce the amount of permitted variability, we should, at a minimum, require food processors to include a disclosure on the food label.

In determining the allowances for variability in § 101.9(g), we considered variability in the nutrient content of foods, analytical variability inherent to test methods used to determine compliance, and statistical probability (38 FR 2125 at 2128, January 19, 1973). In addition, we evaluated compliance procedures and found them to be statistically sound and adequate. The

comment provided no information to support a change to the current level of variance or the use of a disclosure statement in this context.

Therefore, we are not proposing to change the level of variance allowed in § 101.9(g)(5) in response to the comment.

## 2. Methods Used to Determine Compliance

Under § 101.9(g)(2), a composite of 12 subsamples, each taken from 12 different randomly chosen shipping cases are analyzed by appropriate methods as given in the "Official Methods of Analysis of the AOAC International," 15th Ed. (1990) to determine compliance with the requirements in § 101.9, unless a particular method of analysis is specified in § 101.9(c). If no AOAC method is available or appropriate, we use other reliable and appropriate analytical procedures (see § 101.9(g)(2)). The current edition (19th Ed.) of the "Official Methods of Analysis of the AOAC International" includes many updates to the 15th Edition.

When we issued § 101.9(g) related to compliance with nutrition labeling requirements, the most current version of the AOAC methods was its 15th edition and, therefore, we identified the 15th edition in our regulation. Newer and better methods of analysis have been subsequently validated and recognized as "official" methods in the current 19th edition (2012) of the Official Methods of Analysis of the AOAC International. Accordingly, we are proposing to amend § 101.9(g)(2) by removing "15th Ed. (1990)" and adding in its place "19th Ed. (2012)" to specify that we will analyze composites "by appropriate methods as given in the "Official Methods of Analysis of the AOAC International," 19th Ed. (2012)." If a newer edition of the Official Methods of the AOAC International is published before issuance of a final rule, and assuming that we issue a final rule, we intend to finalize this rule with the newer edition, as appropriate, provided there are no substantive changes in the newer edition requiring additional comment.

### 3. Records Requirements

Current § 101.9(g)(2) sets forth requirements for composite sampling and analysis to determine compliance with labeling declarations. Specifically, unless a specific analytical method is identified by regulation, composites are analyzed by the appropriate AOAC method (15th Edition) or, if no AOAC method is available or appropriate, by other reliable and appropriate analytical procedures. For certain nutrients subject to this proposed rule, however, there is no AOAC official method of analysis or other reliable or appropriate analytical procedure that is available for us to verify the amount of the declared nutrient on the Nutrition Facts label and ensure that the declared nutrient amount is truthful, accurate and complies with all applicable labeling requirements, including the requirements in § 101.9(g). Specifically, there is no suitable analytical procedure available to measure the quantity of: (1) Added sugars (when a food product contains both naturally occurring sugars and added sugars and for specific foods containing added sugars, alone or in combination with naturally occurring sugars, where the added sugars are subject to fermentation); (2) dietary fiber (when a food product contains both non-digestible carbohydrate(s) that meets the proposed definition of dietary fiber and non-digestible carbohydrate(s) that does not meet the definition of dietary fiber); (3) soluble fiber (when a mixture of soluble fiber and added non-digestible carbohydrate(s) that does not meet the definition of dietary fiber are present in a food); (4) insoluble fiber (when a mixture of insoluble fiber and non-digestible carbohydrate(s) that does not meet the definition of dietary fiber are present in a food); (5) vitamin E (when a food product contains both RRR- $\alpha$ -tocopherol and all rac- $\alpha$ -tocopherol acetate); and (6) folate (when a food product contains both folate and folic acid). As discussed in sections II.D.3. (added sugars), II.D.5.a. (dietary fiber), II.D.5.b. (soluble and insoluble fiber), II.J.2. (folate), and II.J.3. (vitamin E)

Under current § 101.9(g)(9), FDA may permit the use of an alternative means of compliance or additional exemptions when it is not technologically feasible, or some other circumstance makes it impracticable, for firms to comply with the requirements of § 101.9. In such a case, under § 101.9(g)(9), firms must submit a request in writing to FDA for the use of an alternative means of compliance or for a labeling exemption. We are proposing an alternative approach for assessing compliance of the declared amount of each of the nutrients identified previously under the circumstances we describe, given the nature of the information necessary to determine compliance and the number of foods potentially affected, because there is no suitable analytical method available to measure the quantity of each such nutrient as declared on the label or in labeling. We are proposing to require the manufacturer to make and keep records, identified in proposed § 101.9(g)(10), that are necessary to verify the declared amount of each of these nutrients on the Nutrition Facts label. In proposed § 101.9(g)(10) and (g)(11), we are proposing that manufacturers must make and keep written records, as specified for each of the nutrients and under the circumstances described in proposed § 101.9(g)(10)(i-vii), that are necessary to verify the declared amount. We tentatively conclude that the records will provide the manufacturer and FDA with the necessary means to determine compliance with § 101.9(g) requirements related to nutrient declaration.

The manufacturer is in the best position to know which of its records provide the documentation required under the circumstances described previously for us to determine compliance. Some of the required records may appropriately include one or more of the following: Analyses of databases, recipes or formulations, or batch records. We recognize that the nutrient profile of processed foods that have added sugars, dietary fiber, soluble fiber, insoluble fiber, vitamin E, or folate/folic acid can vary depending on the recipe or formulation,

the suppliers of ingredients, etc. Therefore, the amount of nutrients in a food may change if a manufacturer changes ingredient suppliers or changes a recipe. In order to verify the nutrient composition of a packaged food, the manufacturer would need to ensure that the records it provides to us to verify the declared amount of each of these nutrients, under the circumstances described, substantiate the nutrient composition of the specific food and, as appropriate, can distinguish among the same or similar product the manufacturer has in the marketplace that may contain differing amounts of the declared nutrient. For example, the manufacturer may have to distinguish among different fruit juice products with different amounts of added sugars or the same fruit juice product with different formulations. Most manufacturers should already have the type of records needed to validate the declared amount of each of these nutrients. The records requirements provide flexibility in what records the manufacturer makes available to us to verify the declared amount of these nutrients for a particular marketed product. In the absence of an accurate and reliable analytical method for quantifying the amount of these nutrients for nutrition labeling under the circumstances described, only the manufacturer will have the information required to determine the accuracy of the declared amount. The information contained in manufacturers' records is an accurate and practical method for assuring that the nutrient declarations comply with section 403(q) of the FD&C Act. Under section 403(q) of the FD&C Act, a food must bear, in its label or labeling, the amount of the nutrient the food contains. The purpose of providing the nutritional value of the food is to assist consumers in maintaining health dietary practices. Moreover, the nutrient declaration must be truthful and not misleading under sections 403(a)(1) and 201(n) of the FD&C Act.

Under section 701(a) of the FD&C Act, we may issue regulations for the efficient enforcement of the FD&C Act in order to "effectuate a congressional objective expressed

elsewhere in the Act" (Association of American Physicians and Surgeons, Inc. v FDA, 226 F. Supp. 2d 204 (D.D.C. 2002) (citing Pharm. Mfrs. Ass'n. v FDA, 484 F. Sup. 1179, 1183 (D. Del. 1980)). The proposed record requirements for these nutrients, under the circumstances described, are designed to ensure that the nutrient declarations are accurate, truthful and not misleading, based on information known only to the manufacturer, and to facilitate efficient and effective action to enforce the requirements when necessary. Our authority to establish records requirements has been upheld under other provisions of the FD&C Act where we have found such records to be necessary (National Confectioners Assoc. v Califano, 569 F.2d 690, 693-94 (D.C. Cir. 1978)). The records we propose to require are only for foods for which an AOAC or other reliable and appropriate analytical method is not available. They allow us to verify the declared amount of each of these nutrients and that such amount is truthful and not misleading. Thus, the proposed records requirements assist in the efficient enforcement of the FD&C Act.

The authority granted to us under sections 701(a), 403(q), 403(a)(1) and 201(n) of the FD&C Act not only includes authority to establish records requirements, but also includes access to such records. Without such authority, the nutrient declarations for these specific nutrients that we have determined are necessary to assist consumers in maintaining healthy dietary practices under section 403(q)(2)(A) of the FD&C Act are, practically speaking, not enforceable. Without access to such records, we would not know whether the amount declared on the label or in the labeling of each of these nutrients, under the circumstances described, is truthful and not misleading under sections 403(a)(1) and 201(n). The introduction or delivery for introduction into interstate commerce of a misbranded food is a prohibited act under section 301(a) of the FD&C Act. Thus, in order for us to determine whether the food is misbranded and the

manufacturer has committed a prohibited act, we must have access to the manufacturer's records that we are requiring be kept under sections 403(q), 403(a) and 201(n) of the FD&C Act.

We anticipate that manufacturers may have concerns about the confidentiality of the information inspected by us under this proposal. We would protect confidential information from disclosure, consistent with applicable statutes and regulations, including 5 U.S.C. 552(b)(4), 18 U.S.C. 1905, and 21 CFR part 20.

Finally, it is necessary for the aforementioned records to be made available for review and copying while the product is available for purchase in the marketplace. The shelf life of packaged foods varies by product. Due to the significant number of packaged food products in the marketplace, there could be a wide variety of shelf lives among packaged foods. Some foods are subject to specific records requirements, such as dietary supplements (§ 111.605 (21 CFR 111.605)), low acid canned foods (21 CFR 113.100), acidified foods (21 CFR 114.100), fruit juice (§ 111.120), and seafood (§ 111.123). Therefore, the record retention period we propose to require to verify certain nutrient declarations may include records that manufacturers are required to make and keep for the same or longer periods under other requirements. The proposed record requirements for purposes of verifying nutrient declarations of such nutrients are separate and distinct from other record requirements. Generally, manufacturers are required to make and keep records for a minimum of 2 years (21 CFR 1.360(d)), which the Agency considers a reasonable period of time for most foods to be available for purchase in the marketplace.

Thus, we are proposing to require that manufacturers must make and keep written records to verify the declaration of: (1) The amount of added sugars when both naturally occurring and added sugars are present in a food (in § 101.9(c)(6)(iii)); (2) the amount of added non-digestible

carbohydrate(s) that does not meet the proposed definition of dietary fiber when the dietary fiber present in a food is a mixture of non-digestible carbohydrates that do and that do not meet the definition of dietary fiber (in § 101.9(c)(6)(i)); (3) the amount of added soluble non-digestible carbohydrate(s) that does not meet the proposed definition of dietary fiber when the soluble dietary fiber present in a food is a mixture of soluble non-digestible carbohydrates that do and that do not meet the definition of dietary fiber (in § 101.9(c)(6)(i)(A)); (4) the amount of added insoluble non-digestible carbohydrate(s) that do not meet the proposed definition of dietary fiber when the insoluble dietary fiber present in a food is a mixture of insoluble non-digestible carbohydrates that do and that do not meet the definition of dietary fiber (in § 101.9(c)(6)(i)(B)); (5) the amount of all rac- $\alpha$ -tocopherol acetate added to the food and RRR- $\alpha$ -tocopherol in the finished food when a mixture of both forms of vitamin E are present in a food (in § 101.9(g)(10)(i)); and (6) and the amount of folic acid added to the food and the amount of folate in the finished food when a mixture of both forms are present in a food (in § 101.9(g)(10)(ii)). We are also proposing, in § 101.9(g)(11), that such records must be kept for a period of 2 years after introduction or delivery for introduction of the food into interstate commerce. In addition, we are proposing to require that such records must be provided upon request, during an inspection, for official review and photocopying or other means of reproduction, and that records required may be retained either as original records, true copies (such as photocopies, pictures scanned copies, microfilm, microfiche, or other accurate reproductions of the original records) or electronic records. Where reduction techniques, such as microfilming are used, suitable reader and photocopying equipment would need to be readily available. All electronic records maintained under § 101.9 would need to comply with part 11 of this chapter (§ 101.9(g)(11)). We note that Part 11 would apply to any electronic records that are

maintained to comply with the proposed requirements. We advise that the use of electronic records is voluntary and thus, a paper record system could be used to comply with these proposed recordkeeping requirements. The proposed requirements for electronic records extend to electronic signatures. We issued final guidance for industry on this topic. The guidance, entitled "Part 11, Electronic Records; Electronic Signatures Scope and Application," sets out the Agency's enforcement policies with respect to certain aspects of part 11. The guidance is available at <http://www.fda.gov/RegulatoryInformation/Guidances/ucm125067.htm>. This guidance would apply to any electronic record, including electronic signatures, established or maintained to meet a proposed requirement in this rule, if finalized as proposed. We request comment on the proposed requirements for the types of records that must be made and kept and the length of time that the records must be kept.

#### 4. Inclusion of Potassium as a Mineral

Potassium is specified as a Class I and Class II nutrient in § 101.9(g)(4)(i) and (g)(4)(ii), respectively. This nutrient is the only vitamin or mineral that is specifically listed under the description of both Class I and Class II nutrients. Potassium is a mineral for which an RDI is being proposed (§ 101.9(c)(8)(iv)) and the absolute amount would be required to be declared along with a percent DV on the Nutrition Facts label. We tentatively conclude that there is no need to separately list potassium under the description of Class I and Class II nutrients because it is encompassed within the category, mineral. Therefore, we are proposing to remove specific inclusion of the term "potassium" within § 101.9(g)(4), (g)(4)(i), (g)(4)(ii), and (g)(6) such that it would be covered under "mineral" and any listing of potassium on the Nutrition Facts label would have to meet the specific compliance requirements for minerals under § 101.9(g)(4), (g)(4)(i), (g)(4)(ii), and (g)(6).

## 5. Requirements for Other Carbohydrate, Soluble and Insoluble Fiber, Added Sugars, and Sugar Alcohols

The labeling requirements for Class I and Class II nutrients are provided in section § 101.9(g)(4). For the reasons discussed in section II.D.6., we are proposing to revise § 101.9(c)(6)(iv) to remove the provision for voluntary declaration of "Other carbohydrate." Accordingly, we are proposing to remove compliance requirements related to "Other carbohydrate" in § 101.9(g)(4) and (g)(6).

Dietary fiber is included as both a Class I and Class II nutrient because food products may contain only non-digestible carbohydrates that meet the definition of dietary fiber and that may be naturally occurring or that may be added to fortified or fabricated foods. The same is true for soluble and insoluble fiber, yet these nutrients are not specifically listed as Class I or Class II nutrients. Therefore, we are proposing to include soluble and insoluble fiber in § 101.9(g)(4) as both Class I and Class II nutrients.

Section § 101.9(g)(5) specifies that a food with a label declaration of calories, sugars, total fat, saturated fat, trans fat, cholesterol or sodium shall be deemed to be misbranded under section 403(a) of the FD&C Act if the nutrient content of the composite is greater than 20 percent in excess of the value for that nutrient declared on the label. The nutrients listed in this section can have a negative impact on health in the general U. S. population if consumed in excess and/or there are current dietary recommendations to reduce the consumption of these nutrients. Therefore, we are ensuring in § 101.9(g)(5) that foods do not contain excessive amounts of these nutrients of which the consumer is not aware. Current dietary recommendations acknowledge that Americans consume excess amounts of added sugars and encourage reducing intake of calories from added sugars. As discussed in section II.D.3., added

sugars, like naturally occurring sugars, can contribute to dental caries. As with the other nutrients listed in § 101.9(g)(5), we have an interest in ensuring that foods do not contain excessive amounts of added sugars that are not declared on the label. Therefore, we are proposing to include added sugars in § 101.9(g)(5). In some food products, the only source of sugars may be added sugars. In such cases, an analytical method could be used to determine the amount of added sugars in the food product and the permitted analytical variability would be applicable. Accordingly, we are proposing to amend § 101.9(g)(5) to include "added sugars (when the only source of sugars in the food is added sugars)" among the list of nutrients.

In § 101.9(g)(6), reasonable excesses of certain nutrients over labeled amounts are acceptable within current good manufacturing practice. In addition, reasonable deficiencies of certain other nutrients under labeled amounts are acceptable within current good manufacturing practice. Consistent with this approach, we are proposing to allow, in § 101.9(g)(6), reasonable excesses over the labeled amount of soluble and insoluble fiber and sugar alcohols when they are acceptable within current good manufacturing practice, and reasonable deficiencies under labeled amounts of added sugars when they are acceptable within current good manufacturing practice. As with other nutrients added to fortified or fabricated foods, we expect that when a food product contains added sugars, when all of the dietary fiber (both soluble and insoluble) is added non-digestible carbohydrate that meets the definition of dietary fiber, when all of the vitamin E is all rac- $\alpha$ -tocopherol acetate, and when only folic acid is present in a food, the declared amount must be at least equal to the amount of the nutrient added to the food.

In summary, we are proposing the following changes related to compliance: (1) Amend § 101.9(g)(2) to cite the 19th edition of the Official Methods of Analysis of the AOAC International as the reference for appropriate methods used to determine compliance with

amounts of nutrients declared on the Nutrition Facts label; (2) amend § 101.9(c)(6)(i), (c)(6)(iii), (g)(10), (g)(10)(i), and (g)(10)(ii) to establish general recordkeeping requirements when records are necessary to verify information related to dietary fiber, added sugars, folate, and vitamin E provided on the label; (3) remove specific inclusion of the term "potassium" within § 101.9(g)(4), (g)(4)(i), (g)(4)(ii), and (g)(6) such that potassium would be covered under "mineral" and any listing of potassium on the Nutrition Facts label would meet the specific compliance requirements for minerals under § 101.9(g)(4), (g)(4)(i), (g)(4)(ii), and (g)(6); (4) when all of dietary fiber in a food product meets the proposed definition of dietary fiber, include soluble and insoluble fiber as both Class I and Class II nutrients under § 101.9(g)(4); (5) include added sugars within § 101.9(g)(5) such that the label declaration of added sugars will be deemed misbranded under section 403(a) of the FD&C Act if the nutrient composite is greater than 20 percent in excess of the added sugars value declared on the label, and within § 101.9(g)(6) such that reasonable deficiencies of added sugars would be permitted; (6) include soluble and insoluble fiber and sugar alcohols within § 101.9(g)(6) such that reasonable excesses of these nutrients would be permitted; and (7) consistent with the tentative conclusion in section II.D.6., remove references to "Other carbohydrates" in § 101.9(g).

#### O. Technical Amendments

##### 1. Changing the Name of the Program Office

Since publication of the regulations for nutrition labeling, the name of the office at the Center for Food Safety and Applied Nutrition that is responsible for developing regulations and answering questions related to nutrition labeling as well as for maintaining some of the references discussed throughout § 101.9 has changed. The Office of Nutritional Products,

Labeling and Dietary Supplements is now called the Office of Nutrition, Labeling and Dietary Supplements. We are proposing to update the name of the office throughout § 101.9.

## 2. Changing the Publication Date of Report Incorporated by Reference

Section § 101.9(c)(7)(ii) provides that the protein digestibility-corrected amino acid score "shall be determined by methods given in sections 5.4.1, 7.2.1, and 8.00 in "Protein Quality Evaluation, Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation," Rome, 1990, except that when official AOAC procedures described in section (c)(7) of this paragraph require a specific food factor other than 6.25, that specific factor shall be used." We incorporated the "Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation" by reference in § 101.9(c)(7)(ii). Although the referenced report was written in 1989, it was published in 1991. We are, therefore, proposing to change the publication date of the report that is incorporated by reference from 1990 to 1991.

## 3. Plain Language Edits

On October 13, 2010, the President signed the Plain Writing Act of 2010 requiring that Federal Agencies use "clear Government communication that the public can understand and use." On January 18, 2011, the President issued an Executive Order (E.O. 13563 (75 FR 3821)--Improving Regulation and Regulatory Review) that requires that the government must ensure that regulations are accessible, consistent, written in plain language, and easy to understand. In an effort to make the requirements of § 101.9 easier to understand, we are proposing to make editorial changes that do not change the meaning or intent of the language in § 101.9(g)(3)(ii); (g)(4)(i); (g)(4)(ii); and (g)(5).

In § 101.9(g)(3)(ii), we are revising the current language to clarify that when a nutrient or nutrients are not naturally occurring (exogenous) in an ingredient that is added to a food, the total

amount of such nutrient(s) in the final food product is subject to Class I requirements rather than Class II requirements. It is not explicitly stated in the current regulation that such a nutrient would be subject to Class I requirements.

In § 101.9(g)(4)(i) and (g)(4)(ii), the definitions include a list of vitamins and minerals that are being defined as Class I or Class II vitamins and minerals followed by compliance requirements for those nutrients. This differs from the definition provided in § 101.9(g)(3)(i) and (g)(3)(ii) in that the definitions provided in § 101.9(g)(3)(i) and (g)(3)(ii) are about whether a nutrient is added or naturally occurring. We are proposing to remove "Class I" and "Class II" from the beginning of sections § 101.9(g)(4)(i) and (g)(4)(ii) and to state instead that when the list of nutrients provided in those sections meets the definition of a Class I or Class II nutrient provided for in § 101.9(g)(3)(i) and (g)(3)(ii), the declaration of those nutrients must meet certain requirements. The proposed change is being made to prevent confusion by having two different definitions of a "Class I" and "Class II" nutrient for compliance with nutrition labeling requirements.

In § 101.9(g)(5), we are proposing to remove the words "Provided, That". These words do not provide further clarification and they add additional complexity to the section that is not necessary.

### III. Proposed Effective and Compliance Dates

We intend that any final rule resulting from this rulemaking, as well as any final rule resulting from the proposed rule entitled "Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One-Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments" become effective 60 days after the date of the

final rule's publication in the Federal Register with a compliance date 2 years after the effective date. We recognize that it may take industry time to analyze products for which there may be new mandatory nutrient declarations, make any required changes to the Nutrition Facts label (which may be coordinated with other planned label changes), review and update their records of product labels, and print new labels. A compliance date that is 2 years after the effective date is intended to provide industry time to revise labeling to come into compliance with the new labeling requirements while balancing the need for consumers to have the information in a timely manner. We invite comment on the proposed compliance date.

#### IV. Analysis of Impacts

We have examined the impacts of this proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4) and the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We are publishing two proposed rules on nutrition labeling in the Federal Register. We have developed one comprehensive Preliminary Regulatory Impact Analysis (PRIA) (Ref. 187) that presents the benefits and costs of the two proposed nutrition labeling rules taken together; the PRIA is available at <http://www.regulations.gov> (Docket No. FDA-2012-N-1210). The full economic impact analyses of FDA regulations are no longer (as of April 2012) published in the Federal Register but are submitted to the docket and are available on this site. We believe that the

cumulative impact of the proposed rules on nutrition labeling, taken as a whole, represent a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Additional costs per entity of the proposed rule are small, but not negligible, and as a result we conclude that the proposed rules on nutrition labeling, taken as a whole, would have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that we prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is \$141 million, using the most current (2012) Implicit Price Deflator for the Gross Domestic Product. We have determined that the proposed rules on nutrition labeling, taken as a whole, meet this threshold.

The analysis that we have performed to examine the impacts of the proposed rules under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act, and the PRA (see section V.) are included in the PRIA (Ref. 187) and are available at <http://www.regulations.gov> (Docket No. FDA-2012-N-1210). We invite comment on the PRIA.

#### V. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the PRA. A description of these provisions is given in the PRIA (Ref. 187) available at <http://www.regulations.gov> (Docket No.

FDA-2012-N-1210) with an estimate of the annual reporting, recordkeeping, and third-party disclosure burden. Included in the burden estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

We invite comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the title "Record Retention, Reporting, and Third-Party Disclosure Requirements for the Declaration of Added Sugars, Dietary Fiber, Soluble Fiber, Insoluble Fiber, Vitamin E, and Folate/Folic Acid."

In compliance with the PRA, we have submitted the information collection provisions of this proposed rule to OMB for review. These requirements will not be effective until we obtain OMB approval. We will publish a notice concerning OMB approval of these requirements in the Federal Register.

## VI. Analysis of Environmental Impact

We have carefully considered the potential environmental effects of this action. We have concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required (Refs. 188 and 189). Our finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Division of Dockets Management (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday.

## VII. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive Order requires Agencies to "construe \* \* \* a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute."

Section 403A of the FD&C Act (21 U.S.C. 343-1) is an express preemption provision. Section 403A(a) of the FD&C Act provides that: "\* \* \* no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce--(4) any requirement for nutrition labeling of food that is not identical to the requirement of section 403(q) \* \* \*."

The express preemption provision of section 403A(a) of the FD&C Act does not preempt any State or local requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food (section 6(c)(2) of the Nutrition Labeling and Education Act of 1990, Pub. L. 101-535, 104 Stat. 2353, 2364 (1990)).

If this proposed rule is made final, the final rule would create requirements that fall within the scope of section 403A(a) of the FD&C Act.

#### VIII. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

We invite comment on all aspects of the proposed rule, including the need for, and appropriateness of, the various provisions proposed in this rule and our accompanying rationale. Specifically:

(1) We invite comment on our use of the most recent consensus reports and whether the information and data on which FDA relies from such reports for proposed changes is consistent with current scientific information., the factors for considering mandatory and voluntary declaration of non-statutory nutrients, and whether there is an appropriate alternative analysis to application of these factors regarding (a) no longer permitting mandatory declaration (i.e., vitamins A and C); (b) requiring the declaration of a nutrient that is currently voluntary (e.g., vitamin D), and; (c) continuing the voluntary labeling of macronutrients (e.g., monounsaturated and polyunsaturated fats);

(2) We invite comment on the tentative conclusion to no longer permit the declaration of "Calories from fat" on the Nutrition Facts label and on the tentative conclusion not to establish a

DRV for calories and include a percent DV for the declaration of calories, which are discussed in section II.A;

(3) In section II.B., we addressed various issues related to the declaration of total fat and related nutrients. We invite comment on the proposed definition of fatty acids, as well as on our tentative conclusion that acetic, propionic, and butyric acids should not be excluded from the definition of total fat;

(4) We invite comment on various issues related to the declaration of carbohydrates and related nutrients, which are discussed in section II.D.: (a) With respect to added sugars, we request comments on our tentative conclusions and proposed provisions for mandatory declaration of added sugars, the placement of this information as double indented line below total sugars, and means to verify compliance. We also invite comment, including the submission of available research, on whether calories from added sugars should be declared on the Nutrition Facts label in lieu of a gram declaration of added sugars to aid consumers in maintaining healthy dietary practices. We also invite comment on products that are subjected to non-enzymatic browning reactions and fermentation, and the amount of variability that occurs among various types of products where added sugars are transformed into other compounds as a result of chemical reactions during food processing; (b) with respect to dietary fiber, we invite comment on the proposed definition of dietary fiber and retaining the term "dietary fiber." We invite comment, including the submission of information on consumer understanding of the term "dietary fiber" relative to other relevant terms; and (c) we are proposing to eliminate the provision for voluntary declaration of "Other carbohydrate" on the Nutrition Facts label, and tentatively conclude that the proposed amendment is unlikely to have a significant impact on

industry or consumers. We invite comment on this issue, including the submission of any other data or factual information that we should consider in making a final determination.

(5) We invite comment on our tentative conclusions related to sodium discussed in section II.G., including the proposed DRV. In particular, we invite comment on: (a) The rationale for the proposed DRV of 2,300 for sodium; (b) whether a RDI of 1,500j mg would be more appropriate and why, and; (c) alternative approaches for selecting a DV for sodium and their public health basis for these approaches. We are also interested in comment, including data and factual information on consumer understanding, interpretation, and use of the percent DV of sodium declared on food labels, and the understanding and potential influences of a DV that reflects an RDI based on an AI (an intake level to not consume less of), instead of a DRV based on a UL (an intake level not to exceed);

(6) In section II.H., we are proposing to: (a) Retain mandatory declaration of calcium and iron; (b) provide for voluntary declaration of vitamins A and C; (c) require the declaration of potassium and vitamin D; and (d) retain voluntary declaration of several other vitamins and minerals. We are also proposing to require that all vitamins and minerals declared on the Nutrition Facts label must include their quantitative amounts (in addition to the requirements for corresponding percent DV declaration). We invite comment on these tentative conclusions, including the appropriate placement of the quantitative amounts of nutrients on the Nutrition Facts label, including data and other available information on the impact of mandatory labeling of vitamins and minerals on food fortification. We invite comment on the proposed mandatory declaration of vitamin D, potassium, calcium and iron on the label, including how we consider the public health significance of each. We also invite comment on whether the presence of these nutrients presents concerns related to label space or the need for consumer education. We also

invite comment on whether the presence of these nutrients presents concerns related to label space or the need for consumer education.

(7) In section II.I., we are proposing to use population-coverage RDAs, when available, or AIs as the basis for establishing RDIs. We invite comment on our analysis and rationale, including available data and information related to our analysis, and any available data on what role, if any, the basis of the DV (EAR or RDA) has on consumption of nutrients above the UL and in discretionary fortification of foods; we request comment on lowering the RDI of B<sub>12</sub> to 2.4 µg.

(8) In section II.I.6, whether quantitative amounts for nutrients with RDI values that contain three or four digits should be rounded, what the rounding increments should be, and data to support suggested rounding increments for such vitamins and minerals.

(9) We invite comment on issues related to units of measure, nomenclature, and analytical methods, which are discussed in section II.J.;

(10) We invite comment on issues related to nutrition labeling for foods represented or purported to be specifically for infants 7 through 12 months of age, children 1 through 3 years of age, and pregnant and lactating women, which are addressed in section II.K., including (a) any available relevant empirical research as to whether the proposed declaration of saturated fat and cholesterol for infants and children 1 through 3 years of age is likely to be confusing to consumers or otherwise result in restriction of fat intakes among these subpopulations; (b) how consumers would understand and use the information on amounts of saturated fat and cholesterol in the nutrition labeling of foods for infants and young children and whether there is a need for an explanatory footnote to accompany such proposed mandatory declaration; (c) our tentative conclusion that declaration of added sugars should be mandatory on foods represented or

purported to be specifically for infants 7 through 12 months of age, children 1 through 3 years of age, and pregnant and lactating women; and (d) adequacy of the proposed RDIs for vitamins and minerals for older infants and children 1 through 3 years of age.

(11) We invite comment, including available data and other information on the reformulation of dietary supplement products that may result from proposed changes to the DVs, as well as information on the potential consequences of such reformulations;

(12) We invite comment on whether we should consider changes to the footnote statement "Percent Daily Values are based on a 2,000 calorie diet" used on dietary supplement labels to be consistent with any changes to the footnote statement in the Nutrition Facts label.

(13) We invite comment on (a) including the use of an alternative format design or requiring the use of a specific font; (b) our tentative conclusion that emphasizing both the number of calories per serving and the number of servings per container will serve as an anchor to highlight this information and grab the reader's attention, and therefore will assist consumers to effectively use this information in the Nutrition Facts label; (c) whether any of the changes that are being proposed to the Nutrition Facts label should also be required for certain products with Supplement Facts labels that list calories and/or other macronutrients, and if so, under what conditions and for which dietary supplement products should such labeling be required; (d) our tentative view that there is no need to propose changing the order of how serving size and servings per container are listed on the Supplement Facts label, or to make amendments in the type size or capitalization corresponding to our proposed changes for this information on the Nutrition Facts labels; (e) our tentative conclusion that, based on design considerations, the label statement for "Serving size" in both household units and gram amounts should be right-justified on the same line that "Serving size" is listed; (f) our tentative conclusion that changing the

"Amount Per Serving" statement to "Amount per \_\_\_\_" with the blank filled in with the actual serving size would assist consumers in using the information and may lessen the time and effort needed to locate the target information and improve the accuracy of judgments about the calorie amounts and nutrient contents of packaged food products; (g) the double indented placement of added sugars below total sugars and invite available research data formation; (h) our tentative view that increasing the type size, bolding key elements of the footnote (space permitting), and adding a bar clearly separating it from the micronutrient information directly above will assist consumers in using the information; (i) our tentative view on the need for a footnote statement for enhancing consumers' use and understanding of the percent DV; (j) using data provided consumer research we plan to conduct during this rulemaking that will test consumer reactions to a definition of percent DV, a succinct statement on calories, and several statements related to the "5/20 rule;" (k) whether or not this calorie conversion information should continue to be optional on the Nutrition Facts label, and whether there are any data suggesting that consumers do or do not use this information; (l) alternative terms that may be more readily understandable than Daily Value, such as Daily Guide or Daily Need; (m) whether the word "percent" (or the % symbol) needs to precede whatever term is used in the column heading where the percent DVs are listed; (n) whether there is a need to include vertical lines that are similarly placed on Supplement Facts labels for multiple vitamins in packets (§ 101.36(e)(11)(iii)) and for dietary supplements that list "per serving" and "per day" information (§ 101.36(e)(11)(viii)); (o) the appropriate placement of percent DVs in the labeling of foods for infants 7 through 12 months, children 1 through 3 years of age, and pregnant and lactating women; (p) our tentative conclusion to insert a 0.25 point hairline rule directly beneath the Nutrition Fact heading on all label formats, with the exception of the linear display for small packages; (q) listing the total carbohydrate content in a serving as

"Total Carbs" instead of "Total Carbohydrate" or "Total Carb" and its listing used on all label formats; (r) an alternative concept for the Nutrition Facts label format that indicates "quick facts" about a product's nutrient content and explicitly points out nutrients to "avoid too much" of as well as nutrients to "get enough" of, and; (s) whether a specific font should be required for the Nutrition Facts label. We request comment on how this display may or may not convey the information in a manner which enables the public to readily observe and comprehend such information and whether separating and placing nutrients such as "Total Fat" and "Saturated Fat" under different headings would help or hinder consumer's understanding of the Nutrition Facts label. We also are interested in comments on what headings could be used and how to categorize all of the nutrients.

#### IX. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>. (FDA has verified all the Web site addresses in this reference section, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

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#### List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 101 be amended as follows:

#### PART 101--FOOD LABELING

1. The authority for 21 CFR part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371; 42 U.S.C. 243, 264, 271.

2. In § 101.9:

a. Revise paragraphs (c) introductory text, (c)(1)(i)(A),(c)(1)(i)(C) through (E) (c)(2) introductory text, (c)(5), (c)(6)(i), (c)(6)(iii) and (iv), (c)(7), (c)(8) introductory text, (c)(8)(i), (c)(8)(ii) introductory text, (c)(8)(iii) through (v), (c)(9), (d)(1) introductory text, (d)(1)(ii)(C), (d)(1)(iii) through (v), (d)(2), (d)(3)(i) and (ii), (d)(4) through (8), (d)(10) through (12), (d)(13)(ii), (e), (f) introductory text, (f)(2)(ii), (f)(4) and (5), (g) introductory text, (g)(2), (g)(3)(ii), (g)(4) through (8), (h)(3)(iv), (h)(4) introductory text, (j)(5)(i), (j)(5)(ii) introductory text, (j)(5)(ii)(A), (j)(13)(ii)(A)(1) and (2), (j)(13)(ii)(B) and (C), and (j)(18)(iv) introductory text.

b. Remove paragraph (c)(1)(ii), redesignate paragraph (c)(1)(iii) as (c)(1)(ii), and revise newly designated paragraph (c)(1)(ii);

c. Remove paragraph (c)(6)(iv), redesignate paragraph (c)(6)(iii) as (c)(6)(iv), and add new paragraph (c)(6)(iii);

d. Add paragraphs (c)(1)(i)(F), (c)(8)(vii), (g)(10), and (g)(11);

e. Remove and reserve paragraph (d)(9);

f. Remove paragraphs (e)(3)(i) and (e)(3)(ii); and

j. Remove paragraphs (j)(5)(ii)(B) through (j)(5)(ii)(D), and redesignate paragraph (j)(5)(ii)(E) as (j)(5)(ii)(B).

The revisions read as follows:

§ 101.9 Nutrition labeling of food.

\* \* \* \* \*

(c) The declaration of nutrition information on the label and in labeling of food for adults and children over the age of 4 years, and on foods (other than infant formula) purported to be specifically for infants 7 through 12 months, children 1 through 3 years of age, and pregnant and

lactating women, shall contain information about the level of the following nutrients, except for those nutrients whose inclusion, and the declaration of the amounts, is voluntary as set forth in this paragraph. No nutrients or food components other than those listed in this paragraph as either mandatory or voluntary may be included within the nutrition label. Except as provided for in paragraphs (f) or (j) of this section, nutrient information shall be presented using the nutrient names specified and in the following order in the formats specified in paragraphs (d) or (e) of this section.

(1) \* \* \*

(i) \* \* \*

(A) Using specific Atwater factors (i.e., the Atwater method) given in table 13, "Energy Value of Foods- Basis and Derivation," by A. L. Merrill and B. K. Watt, United States Department of Agriculture (USDA) Handbook No. 74 (slightly revised, 1973), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 and is available from the Office of Nutrition, Labeling, and Dietary Supplements (HFS-800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or may be inspected at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html);

\* \* \* \* \*

(C) Using the general factors of 4, 4, and 9 calories per gram for protein, total carbohydrate (less the amount of non-digestible carbohydrates and sugar alcohols), and total fat, respectively, as described in USDA Handbook No. 74 (slightly revised 1973) pp. 9-11, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 (the availability

of this incorporation by reference is given in paragraph (c)(1)(i)(A) of this section). A general factor of 2 calories per gram for soluble non-digestible carbohydrates shall be used. The general factors for caloric value of sugar alcohols provided in paragraph (c)(1)(i)(F) of this section shall be used;

(D) Using data for specific food factors for particular foods or ingredients approved by the Food and Drug Administration (FDA) and provided in parts 172 or 184 of this chapter, or by other means, as appropriate;

(E) Using bomb calorimetry data subtracting 1.25 calories per gram protein to correct for incomplete digestibility, as described in USDA Handbook No. 74 (slightly revised 1973) p. 10, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 (the availability of this incorporation by reference is given in paragraph (c)(1)(i)(A) of this section);

or

(F) Using the following general factors for caloric value of sugar alcohols: Isomalt--2.0 calories per gram, lactitol--2.0 calories per gram, xylitol--2.4 calories per gram, maltitol--2.1 calories per gram, sorbitol--2.6 calories per gram, hydrogenated starch hydrolysates--3.0 calories per gram, and mannitol--1.6 calories per gram.

(ii) "Calories from saturated fat" or "Calories from saturated" (VOLUNTARY): A statement of the caloric content derived from saturated fat as defined in paragraph (c)(2)(i) of this section in a serving may be declared voluntarily, expressed to the nearest 5-calorie increment, up to and including 50 calories, and the nearest 10-calorie increment above 50 calories, except that amounts less than 5 calories may be expressed as zero. This statement shall be indented under the statement of calories as provided in paragraph (d)(5) of this section.

(2) "Fat, total" or "Total fat": A statement of the number of grams of total fat in a serving defined as total lipid fatty acids and expressed as triglycerides where fatty acids are aliphatic carboxylic acids consisting of a chain of alkyl groups and characterized by a terminal carboxyl group. Amounts shall be expressed to the nearest 0.5 (1/2) gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

\* \* \* \* \*

(5) "Fluoride" (VOLUNTARY): A statement of the number of milligrams of fluoride in a specified serving of food may be declared voluntarily, except that when a claim is made about fluoride content, label declaration shall be required. Fluoride content shall be expressed as zero when the serving contains less than 0.1 milligrams of fluoride, to the nearest 0.1-milligram increment when the serving contains less than or equal to 0.8 milligrams of fluoride, and the nearest 0.2 milligram-increment when a serving contains more than 0.8 milligrams of fluoride.

(6) \* \* \*

(i) "Dietary fiber": A statement of the number of grams of total dietary fiber in a serving, indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, declaration of dietary fiber is not required or, alternatively, the statement "Contains less than 1 gram" or "less than 1 gram" may be used, and if the serving contains less than 0.5 gram, the content may be expressed as zero. Dietary fiber is defined as non-digestible soluble and insoluble carbohydrates (with 3 or more monomeric units) and lignin that are intrinsic and intact in plants; isolated and synthetic non-digestible carbohydrates (with 3 or more monomeric units) that FDA has granted be included in the definition of dietary fiber, in response to a petition submitted to FDA under § 10.30 (21 CFR 10.30) demonstrating that such carbohydrates have a physiological

effect(s) that is beneficial to human health; or isolated and synthetic non-digestible carbohydrates (with 3 or more monomeric units) that are the subject of an authorized health claim. Except as provided for in paragraph (f) of this section, if dietary fiber content is not required, and as a result not declared, the statement "Not a significant source of dietary fiber" shall be placed at the bottom of the table of nutrient values in the same type size. Dietary fiber content may be determined by subtracting the amount of non-digestible carbohydrates added during processing that do not meet the definition of dietary fiber from the value obtained using AOAC 2009.01, AOAC 2011.25, or an equivalent method of analysis as given in the "Official Methods of Analysis of the AOAC International," 19th Ed. (2012), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 in paragraph (g)(2). The following isolated and synthetic non-digestible carbohydrate(s) have been determined by FDA to have physiological effects that are beneficial to human health and, therefore, shall be included in the calculation of the amount of dietary fiber:  $\beta$ -glucan soluble fiber (as described in § 101.81(c)(2)(ii)(A)) and barley  $\beta$ -fiber (as described in § 101.81(c)(2)(ii)(A)(6)).

Manufacturers may submit a citizen petition in accordance with the requirements of § 10.30 to request that FDA allow for the declaration of the gram amount of an isolated and synthetic non-digestible carbohydrate or a health claim petition in accordance with the requirements of § 101.70 for an isolated and synthetic non-digestible carbohydrate. The manufacturer must make and keep records in accordance with paragraphs (g)(10) and (g)(11) of this section to verify the declared amount of dietary fiber in the label and labeling of food when a mixture of dietary fiber, and added non-digestible carbohydrate(s) that does not meet the definition of dietary fiber, is present in the food.

(A) "Soluble fiber" (VOLUNTARY): A statement of the number of grams of soluble dietary fiber in a serving may be declared voluntarily except that when a claim is made on the label or in labeling about soluble fiber, label declaration shall be required. Soluble fiber must meet the definition of dietary fiber in this paragraph (c)(6)(i). Soluble fiber may be determined using AOAC 2011.25 or an equivalent method of analysis as given in the "Official Methods of Analysis of the AOAC International," 19th Ed. (2012), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 in paragraph (g)(2). The manufacturer must make and keep records in accordance with paragraphs (g)(10) and (g)(11) of this section to verify the declared amount of soluble fiber in the label and labeling of food when a mixture of soluble fiber and added non-digestible carbohydrate(s) that does not meet the definition of dietary fiber is present in the food. Soluble fiber content shall be indented under dietary fiber and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero."

(B) "Insoluble fiber" (VOLUNTARY): A statement of the number of grams of insoluble dietary fiber in a serving may be declared voluntarily except that when a claim is made on the label or in labeling about insoluble fiber, label declaration shall be required. Insoluble fiber must meet the definition of dietary fiber in this paragraph (c)(6)(i). Insoluble fiber may be determined using AOAC 2011.25 or an equivalent method of analysis as given in the "Official Methods of Analysis of the AOAC International," 19th Ed. (2012), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 in paragraph (g)(2) of this section. The manufacturer must make and keep records in accordance with paragraphs (g)(10) and (g)(11) of this section to verify the declared amount of insoluble fiber in the label and labeling of food

when a mixture of insoluble and added non-digestible carbohydrate(s) that does not meet the definition of dietary fiber is present in the food. Insoluble fiber content shall be indented under dietary fiber and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero."

\* \* \* \* \*

(iii) "Added Sugars": A statement of the number of grams of added sugars in a serving, except that label declaration of added sugars content is not required for products that contain less than 1 gram of added sugars in a serving if no claims are made about sweeteners, sugars, added sugars, or sugar alcohol content. If a statement of the added sugars content is not required and, as a result, not declared, the statement "Not a significant source of added sugars" shall be placed at the bottom of the table of nutrient values in the same type size. Added sugars shall be defined as sugars that are either added during the processing of foods, or are packaged as such, and include sugars (free, mono- and disaccharides), syrups, naturally occurring sugars that are isolated from a whole food and concentrated so that sugar is the primary component (e.g., fruit juice concentrates), and other caloric sweeteners. Added sugars content shall be indented under sugars and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero. When a mixture of naturally occurring and added sugars is present in the food, and for specific foods containing added sugars, alone or in combination with naturally occurring sugars, where the added sugars are subject to fermentation, the manufacturer must make and keep records in accordance with

paragraphs (g)(10) and (g)(11) of this section to verify the declared amount of added sugars in the label and labeling of food.

(iv) "Sugar alcohol" (VOLUNTARY): A statement of the number of grams of sugar alcohols in a serving may be declared voluntarily on the label, except that when a claim is made on the label or in labeling about sugar alcohol or sugars when sugar alcohols are present in the food, sugar alcohol content shall be declared. For nutrition labeling purposes, sugar alcohols are defined as the sum of saccharide derivatives in which a hydroxyl group replaces a ketone or aldehyde group and whose use in the food is listed by FDA (e.g., mannitol or xylitol) or is generally recognized as safe (e.g., sorbitol). In lieu of the term "sugar alcohol," the name of the specific sugar alcohol (e.g., "xylitol") present in the food may be used in the nutrition label provided that only one sugar alcohol is present in the food. Sugar alcohol content shall be indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(7) "Protein": A statement of the number of grams of protein in a serving, expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero. When the protein in foods represented or purported to be for adults and children 4 or more years of age has a protein quality value that is a protein digestibility-corrected amino acid score of less than 20 expressed as a percent, or when the protein in a food represented or purported to be for children greater than 1 but less than 4 years of age has a protein quality value that is a protein digestibility-corrected amino acid score of less than 40 expressed as a percent, either of the following shall be placed adjacent to the

declaration of protein content by weight: The statement "not a significant source of protein," or a listing aligned under the column headed "Percent Daily Value" of the corrected amount of protein per serving, as determined in paragraph (c)(7)(ii) of this section, calculated as a percentage of the Daily Reference Value (DRV) or Reference Daily Intake (RDI), as appropriate, for protein and expressed as a Percent of Daily Value. When the protein quality in a food as measured by the Protein Efficiency Ratio (PER) is less than 40 percent of the reference standard (casein) for a food represented or purported to be specifically for infants 7 through 12 months, the statement "not a significant source of protein" shall be placed adjacent to the declaration of protein content. Protein content may be calculated on the basis of the factor 6.25 times the nitrogen content of the food as determined by the appropriate method of analysis as given in the "Official Methods of Analysis of the AOAC International," 19th Ed. (2012), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, except when the official procedure for a specific food requires another factor. Copies may be obtained from AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be inspected at the National Archives and Records Administration (NARA). For more information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(i) A statement of the corrected amount of protein per serving, as determined in paragraph (c)(7)(ii) of this section, calculated as a percentage of the RDI or DRV for protein, as appropriate, and expressed as Percent of Daily Value, may be placed on the label, except that such a statement shall be given if a protein claim is made for the product, or if the product is represented or purported to be specifically for infants 7 through 12 months or children 1 through 3 years of age. When such a declaration is provided, it should be placed on the label adjacent to

the statement of grams of protein and aligned under the column headed "Percent Daily Value," and expressed to the nearest whole percent. However, the percentage of the RDI for protein shall not be declared if the food is represented or purported to be specifically for infants 7 through 12 months and the protein quality value is less than 40 percent of the reference standard.

(ii) The "corrected amount of protein (gram) per serving" for foods represented or purported for adults and children 1 or more years of age is equal to the actual amount of protein (gram) per serving multiplied by the amino acid score corrected for protein digestibility. If the corrected score is above 1.00, then it shall be set at 1.00. The protein digestibility-corrected amino acid score shall be determined by methods given in sections 5.4.1, 7.2.1, and 8.00 in "Protein Quality Evaluation, Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation," Rome, 1991, except that when official AOAC procedures described in this paragraph (c)(7) require a specific food factor other than 6.25, that specific factor shall be used. The "Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation" as published by the Food and Agriculture Organization of the United Nations/World Health Organization is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 and is available from the Office of Nutrition, Labeling, and Dietary Supplements (HFS-800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or may be inspected at the National Archives and Records Administration (NARA). For more information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html). For foods represented or purported to be specifically for infants 7 through 12 months, the corrected amount of protein (grams) per serving is equal to the actual amount of protein (grams) per

servings multiplied by the relative protein quality value. The relative protein quality value shall be determined by dividing the subject food protein PER value by the PER value for casein. If the relative protein value is above 1.00, it shall be set at 1.00.

(iii) For the purpose of labeling with a percent of the DRV or RDI, a value of 50 grams of protein shall be the DRV for adults and children 4 or more years of age, a value of 11 grams of protein shall be the RDI for infants 7 through 12 months, a value of 13 grams shall be the DRV for children 1 through 3 years of age, and a value of 71 grams of protein shall be the RDI for pregnant and lactating women.

(8) Vitamins and minerals: A statement of the amount per serving of the vitamins and minerals as described in this paragraph, expressed as a quantitative amount by weight using the appropriate unit of measure provided in paragraph (c)(8)(iv) of this section and as a percent of Daily Value calculated as a percent of the RDI provided in paragraph (c)(8)(iv) of this section.

(i) For purposes of declaration of percent of Daily Value as provided for in paragraphs (d), (e), and (f) of this section, foods represented or purported to be specifically for infants 7 through 12 months, children 1 through 3 years, and pregnant and lactating women shall use the RDIs that are specified for the intended group. For foods represented or purported to be specifically for both infants 7 through 12 months and children 1 through 3 years of age, the percent of Daily Value shall be presented by separate declarations according to paragraph (e) of this section based on the RDI values for infants 7 through 12 months and children 1 through 3 years of age. When such dual declaration is used on any label, it shall be included in all labeling, and equal prominence shall be given to both values in all such labeling. The percent Daily Value based on the RDI values for pregnant and lactating women shall be declared on food represented

or purported to be specifically for pregnant and lactating women. All other foods shall use the RDI for adults and children 4 or more years of age.

(ii) The declaration of vitamins and minerals as a quantitative amount by weight and percent of the RDI shall include vitamin D, calcium, iron, and potassium in that order, for infants 7 through 12 months, children 1 through 3 years of age, pregnant and lactating women, and adults and children 4 or more years of age. The declaration of vitamins and minerals as a quantitative amount by weight and percent of the RDI shall include any of the other vitamins and minerals listed in paragraph (c)(8)(iv) of this section when they are added as a nutrient supplement, or when a claim is made about them. Other vitamins and minerals need not be declared if neither the nutrient nor the component is otherwise referred to on the label or the labeling or advertising and the vitamins and minerals are:

\* \* \* \* \*

(iii) The percentages for vitamins and minerals shall be expressed to the nearest 2-percent increment above 10 percent and up to and including the 50-percent level. Quantitative amounts and percentages of vitamins and minerals present at less than 2 percent of the RDI are not required to be declared in nutrition labeling but may be declared by a zero or by the use of an asterisk (or other symbol) that refers to another asterisk (or symbol) that is placed at the bottom of the table and that is followed by the statement "Contains less than 2 percent of the Daily Value of this (these) nutrient (nutrients)" or "Contains < 2 percent of the Daily Value of this (these) nutrient (nutrients)." Alternatively, except as provided for in paragraph (f) of this section, if vitamin D, calcium, iron, or potassium is present in amounts less than 2 percent of the RDI, label declaration of the nutrient(s) is not required if the statement "Not a significant source of \_\_\_ (listing the vitamins or minerals omitted)" is placed at the bottom of the table of nutrient

values. Either statement shall be in the same type size as nutrients that are indented. The quantitative amounts of vitamins and minerals, excluding sodium, shall be the amount of the vitamin or mineral included in one serving of the product, using the units of measurement and the levels of significance given in paragraph (c)(8)(iv) of this section, except that zeros following decimal points may be dropped, and additional levels of significance may be used when the number of decimal places indicated is not sufficient to express lower amounts (e.g., the RDI for zinc is given in whole milligrams, but the quantitative amount may be declared in tenths of a milligram).

(iv) The following RDIs, nomenclature, and units of measure are established for the following vitamins and minerals which are essential in human nutrition:

Nutrient	Unit of Measure	RDI			
		Adults and Children $\geq$ 4 Years	Infants 7 Through 12 Months	Children 1 Through 3 Years	Pregnant and Lactating Women
Vitamin A	Micrograms RAE <sup>1</sup> (mcg)	900	500	300	1,300
Vitamin C	Milligrams (mg)	90	50	15	120
Calcium	Milligrams (mg)	<u>1,300</u>	<u>260</u>	<u>700</u>	<u>1,300</u>
Iron	Milligrams (mg)	<u>18</u>	<u>11</u>	<u>7</u>	<u>27</u>
Vitamin D	Micrograms (mcg)	<u>20</u>	<u>10</u>	<u>15</u>	<u>15</u>
Vitamin E	Milligrams (mg)	15	5	6	19
Vitamin K	Micrograms (mcg)	120	2.5	30	90
Thiamin	Milligrams (mg)	1.2	0.3	0.5	1.4
Riboflavin	Milligrams (mg)	1.3	0.4	0.5	1.6
Niacin	Milligrams NE <sup>2</sup> (mg)	16	4	6	18
Vitamin B <sub>6</sub>	Milligrams (mg)	1.7	0.3	0.5	2.0
Folate <sup>3</sup>	Micrograms DFE <sup>4</sup> (mcg)	400	80	150	600
Vitamin B <sub>12</sub>	Micrograms (mcg)	2.4	0.5	0.9	2.8

Nutrient	Unit of Measure	RDI			
		Adults and Children $\geq$ 4 Years	Infants 7 Through 12 Months	Children 1 Through 3 Years	Pregnant and Lactating Women
Biotin	Micrograms (mcg)	30	6	8	35
Pantothenic acid	Milligrams (mg)	5	1.8	2	7
Phosphorous	Milligrams (mg)	1,250	275	460	1,250
Iodine	Micrograms (mcg)	150	130	90	290
Magnesium	Milligrams (mg)	420	75	80	400
Zinc	Milligrams (mg)	11	3	3	13
Selenium	Micrograms (mcg)	55	20	20	70
Copper	Milligrams (mg)	0.9	0.2	0.3	1.3
Manganese	Milligrams (mg)	2.3	0.6	1.2	2.6
Chromium	Micrograms (mcg)	35	5.5	11	45
Molybdenum	Micrograms (mcg)	45	3	17	50
Chloride	Milligrams (mg)	2,300	570	1500	2300
Potassium	Milligrams (mg)	<u>4,700</u>	<u>700</u>	<u>3000</u>	<u>5100</u>
Choline	Milligrams (mg)	550	150	200	550
Protein	Grams (g)	<u>N/A</u>	<u>11</u>	<u>N/A</u>	<u>71</u> <sup>5</sup>

A percent daily value must be declared on the label for bolded nutrients.

<sup>1</sup>RAE = Retinol activity equivalents; 1 RAE = 1 microgram retinol, 12 micrograms  $\beta$ -carotene, or 24 micrograms  $\alpha$ -carotene, or 24 micrograms  $\beta$ -cryptoxanthin.

<sup>2</sup>NE = Niacin equivalents, 1 milligram niacin = 60 milligrams of tryptophan.

<sup>3</sup>"Folic Acid" must be used for purposes of declaration in the labeling of dietary supplements. It must also be declared in mcg DFE.

<sup>4</sup>DFE = Dietary folate equivalents; 1 DFE = 1 microgram food folate = 0.6 micrograms folic acid from fortified food or as a supplement consumed with food = 0.5 micrograms of a supplement.

<sup>5</sup>Based on the reference caloric intake of 2,000 calories for adults and children aged 4 years and older, and for pregnant and lactating women.

(v) The following synonyms may be added in parentheses immediately following the name of the nutrient or dietary component:

Calories--Energy

Vitamin C--Ascorbic acid

Thiamin--Vitamin B<sub>1</sub>

Riboflavin--Vitamin B<sub>2</sub>

\* \* \* \* \*

(vii) When the amount of folate is declared in the labeling of a conventional food, the nutrient name "folate" shall be listed for products containing either folate alone or a mixture of folate and folic acid. The name of the synthetic form of the nutrient, "folic acid" shall be used when the nutrient is declared in the labeling of dietary supplements.

(9) The following DRVs, nomenclature, and units of measure are established for the following food components:

Food Component	Unit of Measurement	DRV			
		Adults and Children ≥ 4 years	Infants 7 Through 12 Months	Children 1 Through 3 Years	Pregnant and Lactating Women
Fat	Grams (g)	65 <sup>1</sup>	30	39 <sup>2</sup>	65 <sup>1</sup>
Saturated fatty acids	Grams (g)	20 <sup>1</sup>	N/A	10 <sup>2</sup>	20 <sup>1</sup>
Cholesterol	Milligrams (mg)	300	N/A	300	300
Total carbohydrate	Grams (g)	300 <sup>1</sup>	95	150 <sup>2</sup>	300 <sup>1</sup>
Sodium	Milligrams (mg)	2,300	N/A	1,500	2,300
Dietary fiber	Grams (g)	28 <sup>1</sup>	N/A	14 <sup>2</sup>	28 <sup>1</sup>
Protein	Grams (g)	50 <sup>1</sup>	N/A	13 <sup>2</sup>	N/A

<sup>1</sup>Based on the reference caloric intake of 2,000 calories for adults and children aged 4 years and older, and for pregnant and lactating women

<sup>2</sup>Based on the reference caloric intake of 1,000 calories for children 1 through 3 years of age.

(d)(1) Nutrient information specified in paragraph (c) of this section shall be presented on foods in the following format, as shown in paragraph (d)(12) of this section, except on foods where the tabular display is permitted as provided for in paragraph (d)(11) of this section, on which dual columns of nutrition information are declared as provided for in paragraph (e) of this

section, on those food products on which the simplified format is required to be used as provided for in paragraph (f) of this section, on foods for infants 7 months to 12 months of age and children 1 through 3 years of age as provided for in paragraph (j)(5) of this section, and on foods in small or intermediate-sized packages as provided for in paragraph (j)(13) of this section. In the interest of uniformity of presentation, FDA strongly recommends that the nutrition information be presented using the graphic specifications set forth in appendix B to part 101.

\* \* \* \* \*

(ii) \* \* \*

(C) At least nine points leading (i.e., space between two lines of text) except that at least 12 points leading shall be utilized for the information required by paragraphs (d)(7) and (d)(8) of this section as shown in paragraph (d)(12), and

\* \* \* \* \*

(iii) Information required in paragraphs (d)(7) and (d)(8) of this section shall be in type size no smaller than 8 point, except the type size for this information required in the linear display for small packages as shown in paragraph (j)(13)(ii)(A)(2) of this section shall be no smaller than 7 point. Information required in the footnote statement shall be no smaller than 7 point, except the type size for this information required in the tabular display for small packages as shown in paragraph (j)(13)(ii)(A)(1) of this section, for the linear display for small packages as shown in paragraph (j)(13)(ii)(A)(2) of this section, and for the simplified format as shown in paragraph (f)(5) of this section shall be no smaller than 6 point. Information required in paragraph (d)(5) of this section for the "Calories" declaration shall be highlighted in bold or extra bold and shall be in a type size no smaller than 16 point except the type size for this information required in the tabular display for small packages as shown in paragraph (j)(13)(ii)(A)(1) of this

section, the linear display for small packages as shown in paragraph (j)(13)(ii)(A)(2) of this section, and the required information shown in paragraphs (d)(11)(iii) and (e)(6)(ii) of this section shall be in a type size no smaller than 12 point. The numeric amount for the information required in paragraph (d)(5) of this section shall also be highlighted in bold or extra bold type and shall be in a type size no smaller than 24 point, except the type size for this information required in the tabular display for small packages as shown in paragraph (j)(13)(ii)(A)(1) of this section, the linear display for small packages as shown in paragraph (j)(13)(ii)(A)(2) of this section, and for the required information shown in paragraph (e)(6)(ii) of this section shall be in a type size no smaller than 20 point. The information required in paragraph (d)(6) of this section shall be in a type size no smaller than 7 point. When provided, the information described in paragraph (d)(10) of this section shall be in a type size no smaller than 6 point.

(iv) The headings required by paragraphs (d)(2), (d)(3)(i), and (d)(6) of this section (i.e., "Nutrition Facts," "\_\_servings per container," and "% DV\*"), the calorie information, and the names of all nutrients that are not indented according to requirements of paragraph (c) of this section (i.e., "Calories," "Total Fat," "Cholesterol," "Sodium," "Total Carbs" and "Protein"), and the percentage amounts required by paragraph (d)(7)(ii) of this section shall be highlighted in bold or extra bold type or other highlighting (reverse printing is not permitted as a form of highlighting) that prominently distinguishes it from other information. The names of all nutrients that are indented according to the requirements of paragraph (c) of this section (i.e., "Saturated Fat," "Trans Fat," "Dietary Fiber," "Sugars," and "Added Sugars") and the mandatory and any voluntary vitamins and minerals (except sodium), shall be highlighted in a type that is intermediate between bold or extra bold type and the type for all other information.

(v) A hairline rule that is centered between the lines of text shall separate "Nutrition Facts" from the servings per container statement required in paragraph (d)(3)(i) of this section and shall separate each nutrient and its corresponding percent Daily Value required in paragraphs (d)(7)(i) and (d)(7)(ii) of this section from the nutrient and percent Daily Value above and below it, as shown in paragraph (d)(12) of this section.

(2) The information shall be presented under the identifying heading of "Nutrition Facts" in the nutrition label and, except for labels presented according to the format provided for in paragraphs (d)(11)(iii), (d)(13)(ii), (e)(6)(ii), (j)(13)(ii)(A)(1), and (j)(13)(ii)(A)(2) of this section, unless impractical, shall be set the full width of the information provided under paragraph (d)(7) of this section, as shown in paragraph (d)(12) of this section.

(3) \* \* \*

(i) "   servings per container": The number of servings per container, except that this statement is not required on single serving containers as defined in paragraph (b)(6) of this section or on other food containers when this information is stated in the net quantity of contents declaration. The information required in this paragraph shall be highlighted in bold or extra bold and be in a type size no smaller than 11 point except the type size shall be no smaller than 10 point for this information as shown in paragraph (j)(13)(ii)(A)(1) and no smaller than 7 point as shown in paragraph (j)(13)(ii)(A)(2) of this section. This information shall be set the full width of the label as shown in paragraph (d)(12) of this section.

(ii) "Serving size": A statement of the serving size as specified in paragraph (b)(7) of this section. The serving size as specified in paragraph (b)(7) of this section must be right justified as shown in paragraph (d)(12) of this section. The information required in this paragraph shall be

in a type size no smaller than 8 point except the type size shall be no smaller than 7 point for this information as shown in paragraph (j)(13)(ii)(A)(2) of this section.

(4) A subheading "Amount per" followed by the serving size shall be separated from the serving size information by a bar as shown in paragraph (d)(12) of this section and shall be highlighted in a type that is intermediate between bold or extra bold type and the type for all other information, and be in a type size no smaller than 8 point, except the type size for this information required in the linear display for small packages as shown in paragraph (j)(13)(ii)(A)(2) and the tabular display for small packages as shown in paragraph (j)(13)(ii)(A)(1) of this section shall be no smaller than 6 point, and there shall be no bar separating this information from the serving size information in both of these displays for small packages.

(5) Information on calories shall immediately follow the heading "Amount per" followed by the serving size and shall be declared in one line. If "Calories from saturated fat" is declared, it shall be indented under "Calories" and shall be in a type size no smaller than 8 point.

(6) The column heading "% DV," followed by an asterisk (e.g., "% DV\*"), shall be separated from information on calories by a bar as shown in paragraph (d)(12) of this section. The position of this column heading shall allow for a list of nutrient names and amounts as described in paragraph (d)(7) of this section to be to the right of, and below, this column heading, except for labels with a dual or multiple column format as shown in paragraphs (d)(13)(ii), (e)(5), (e)(6)(i), and (e)(6)(ii) the "% DV" column will appear to the right of the list of nutrient names. The column heading described in this paragraph shall not appear on the linear display for small packages as shown in paragraph (j)(13)(ii)(A)(2) of this section.

(7) Except as provided for in paragraphs (d)(13)(ii), (e)(5), (e)(6)(i), (e)(6)(ii), and (j)(13) of this section, nutrient information for both mandatory and any voluntary nutrients listed in paragraph (c) of this section that are to be declared in the nutrition label shall be declared as follows:

(i) The name of each nutrient, as specified in paragraph (c) of this section, shall be given in a column and followed immediately by the quantitative amount by weight for that nutrient appended with a "g" for grams, "mg" for milligrams, or "mcg" for micrograms as shown in paragraph (d)(12) of this section. The symbol "<" may be used in place of "less than."

(ii) A listing of the percent of the DRV as established in paragraphs (c)(7)(iii) and (c)(9) of this section shall be given in a column aligned under the heading "% DV" established in paragraph (d)(6) of this section with the percent expressed to the nearest whole percent for each nutrient declared in the column described in paragraph (d)(7)(i) of this section for which a DRV has been established, except that the percent for protein may be omitted as provided in paragraph (c)(7) of this section. The percent shall be calculated by dividing either the amount declared on the label for each nutrient or the actual amount of each nutrient (i.e., before rounding) by the DRV for the nutrient, except that the percent for protein shall be calculated as specified in paragraph (c)(7)(ii) of this section. The numerical value shall be followed by the symbol for percent (i.e., %).

(8) Nutrient information for vitamins and minerals (except sodium) shall be separated from information on other nutrients by a bar and may be arrayed vertically as shown in paragraph (d)(12) of this section (e.g., Vitamin D 2mcg (10%), Calcium 260mg (20%), Iron 8mg (45%), Potassium 235mg (5%)) or may be listed in two columns. When listed horizontally in

two columns, vitamin D and calcium should be listed on the first line and iron and potassium should be listed on the second line.

(9) [Reserved]

(10) Caloric conversion information on a per gram basis for fat, carbohydrate, and protein may be presented beneath the information required in the footnote statement, separated from that information by a hairline. This information may be presented horizontally as shown in paragraph (d)(12) of this section (i.e. “Calories per gram: fat 9, carbohydrate 4, protein 4”) or vertically in columns.

(11)(i) If the space beneath the information on vitamins and minerals is not adequate to accommodate the information required in the footnote statement, the information required in the footnote statement may be moved to the right of the column required in paragraph (d)(7)(ii) of this section and set off by a line that distinguishes it and sets it apart from the percent Daily Value information. The caloric conversion information provided for in paragraph (d)(10) of this section may be presented beneath either side or along the full length of the nutrition label.

(ii) If the space beneath the mandatory declaration of potassium is not adequate to accommodate any remaining vitamins and minerals to be declared or the information required in the footnote statement, the remaining information may be moved to the right and set off by a line that distinguishes it and sets it apart from the nutrients and the percent DV information given to the left. The caloric conversion information provided for in paragraph (d)(10) of this section may be presented beneath either side or along the full length of the nutrition label.

(iii) If there is not sufficient continuous vertical space (i.e., approximately 3 in) to accommodate the required components of the nutrition label up to and including the mandatory

declaration of potassium, the nutrition label may be presented in a tabular display as shown in the following sample label.

<b>Nutrition Facts</b>	<b>% DV* amount per 2 slices</b>		<b>% DV* amount per 2 slices</b>		* Footnote on Daily Values (DV) and calories reference to be inserted here.
	<b>2%</b>	<b>Total Fat</b> 1.5g	<b>12%</b>	<b>Total Carbs</b> 36g	
<b>10 servings</b> Serving size 2 slices (56g)	<b>3%</b>	<b>Saturated Fat</b> 0.5g	<b>7%</b>	<b>Dietary Fiber</b> 2g	
		<i>Trans Fat</i> 0.5g		<b>Sugars</b> 1g	
<b>170 Calories</b> Per 2 slices	<b>0%</b>	<b>Cholesterol</b> 0mg		<b>Added</b> 1g	
	<b>12%</b>	<b>Sodium</b> 280mg		<b>Protein</b> 4g	
0% <b>Vitamin D</b> 0mcg • 6% <b>Calcium</b> 80mg • 6% <b>Iron</b> 1mg • 10% <b>Potassium</b> 470mg 15% <b>Thiamin</b> 0.2mg • 8% <b>Riboflavin</b> 0.1mg • 10% <b>Niacin</b> 1.6mg					

(12) The following sample labels illustrate the mandatory provisions and mandatory plus voluntary provisions of paragraph (d) of this section.

<b>Nutrition Facts</b>	
<b>8 servings per container</b>	
Serving size	2/3 cup (55g)
<b>Amount per 2/3 cup</b>	
<b>Calories</b>	<b>230</b>
% DV*	
<b>12%</b>	<b>Total Fat</b> 8g
<b>5%</b>	<b>Saturated Fat</b> 1g
	<i>Trans Fat</i> 0g
<b>0%</b>	<b>Cholesterol</b> 0mg
<b>7%</b>	<b>Sodium</b> 160mg
<b>12%</b>	<b>Total Carbs</b> 37g
<b>14%</b>	<b>Dietary Fiber</b> 4g
	<b>Sugars</b> 1g
	<b>Added Sugars</b> 0g
	<b>Protein</b> 3g
10%	<b>Vitamin D</b> 2mcg
20%	<b>Calcium</b> 260mg
45%	<b>Iron</b> 8mg
5%	<b>Potassium</b> 235mg
* Footnote on Daily Values (DV) and calories reference to be inserted here.	

<b>Nutrition Facts</b>	
<b>17 servings per container</b>	
Serving size	3/4 cup (28g)
<b>Amount per 3/4 cup</b>	
<b>Calories</b>	<b>140</b>
% DV*	
<b>2%</b>	<b>Total Fat</b> 1.5g
<b>0%</b>	<b>Saturated Fat</b> 0g
	<i>Trans Fat</i> 0g
	<b>Polyunsaturated Fat</b> 0.5g
	<b>Monounsaturated Fat</b> 0.5g
<b>0%</b>	<b>Cholesterol</b> 0mg
<b>7%</b>	<b>Sodium</b> 160mg
<b>7%</b>	<b>Total Carbs</b> 22g
<b>7%</b>	<b>Dietary Fiber</b> 2g
	<b>Soluble Fiber</b> <1g
	<b>Insoluble Fiber</b> 1g
	<b>Sugars</b> 9g
	<b>Added Sugars</b> 8g
<b>18%</b>	<b>Protein</b> 9g
10%	<b>Vitamin D</b> 2mcg
10%	<b>Calcium</b> 130mg
25%	<b>Iron</b> 4.5mg
2%	<b>Potassium</b> 115mg
10%	<b>Vitamin A</b> 90mcg
10%	<b>Vitamin C</b> 9mg
25%	<b>Thiamin</b> 0.3mg
25%	<b>Riboflavin</b> 0.3mg
25%	<b>Niacin</b> 4mg
25%	<b>Vitamin B<sub>6</sub></b> 0.4mg
50%	<b>Folic Acid</b> 200mcg DFE
25%	<b>Vitamin B<sub>12</sub></b> 0.6mcg
8%	<b>Phosphorus</b> 100mg
6%	<b>Magnesium</b> 25mg
25%	<b>Zinc</b> 3mg
Calories per gram: <b>Fat 9 • Carbohydrate 4 • Protein 4</b>	
* Footnote on Daily Values (DV) and calories reference to be inserted here.	

(13) \* \* \*

(ii) Aggregate displays shall comply with the format requirements of paragraph (d) of this section to the maximum extent possible, except that the identity of each food shall be specified immediately to the right of the "Nutrition Facts" heading, and both the quantitative amount by weight (i.e., g/mg/mcg amounts) and the percent Daily Value for each nutrient shall be listed in separate columns under the name of each food. The following sample label illustrates an aggregate display.

<b>Nutrition Facts</b> <b>1 serving per container</b> Serving size 1 box	Wheat Squares Sweetened	Corn Flakes Not Sweetened	Mixed Grain Flakes Sweetened
	Amount per box (35g)	Amount per box (19g)	Amount per box (27g)
<b>Calories</b> (amount per box)	<b>130</b>	<b>70</b>	<b>100</b>
<b>Total Fat</b>	<b>% DV*</b>	<b>% DV*</b>	<b>% DV*</b>
Saturated Fat	0% 0g	0% 0g	0% 0g
Trans Fat	0% 0g	0% 0g	0% 0g
<b>Cholesterol</b>	0% 0mg	0% 0mg	0% 0mg
<b>Sodium</b>	0% 0mg	9% 200mg	5% 120mg
<b>Total Carbs</b>	10% 29g	6% 17g	8% 24g
Dietary Fiber	11% 3g	4% 1g	4% 1g
Sugars	8g	6g	13g
Added Sugars	8g	5g	13g
<b>Protein</b>	4g	1g	1g
* Footnote on Daily Values (DV) and calories reference to be inserted here.	<b>Vitamin D</b> 10% 2mcg	10% 2mcg	0% 0mcg
	<b>Calcium</b> 0% 0mg	0% 0mg	0% 0mg
	<b>Iron</b> 10% 2mg	6% 1mg	20% 4mg
	<b>Potassium</b> 4% 125mg	0% 25mg	0% 30mg
	<b>Vitamin A</b> 0% 0mcg	10% 90mcg	10% 90mcg
	<b>Vitamin C</b> 0% 0mg	15% 14mg	90% 80mg
	<b>Thiamin</b> 35% 0.4mg	15% 0.2mg	25% 0.3mg
	<b>Riboflavin</b> 30% 0.4mg	15% 0.2mg	25% 0.3mg
	<b>Niacin</b> 30% 5mg	15% 2mg	20% 3mg
	<b>Vitamin B<sub>6</sub></b> 30% 0.5mg	20% 0.3mg	20% 0.3mg

\* \* \* \* \*

(e) Nutrition information may be presented for two or more forms of the same food (e.g., both "as purchased" and "as prepared") or for common combinations of food as provided for in paragraph (h)(4) of this section, for different units (e.g., slices of bread or per 100 grams) as provided for in paragraph (b) of this section, or for two or more groups for which RDIs are established (e.g., both infants 7 through 12 months and children 1 through 3 years of age) as shown in paragraph (e)(5) of this section. When such dual labeling is provided, equal prominence shall be given to both sets of values. Information shall be presented in a format consistent with paragraph (d) of this section, except that:

(1) Following the serving size information there shall be two or more column headings accurately describing the amount per serving size of the form of the same food (e.g., "Per ¼ cup mix" and "Per prepared portion"), the combinations of food, the units, or the RDI groups that are being declared as shown in paragraph (e)(5) of this section.

(2) The information required in paragraph (d)(7)(ii) and the quantitative information by weight as required in paragraph (d)(7)(i) of this section shall be presented for the form of the product as packaged and for any other form of the product (e.g., "as prepared" or combined with another ingredient as shown in paragraph (e)(5) of this section).

(3) When the dual labeling is presented for two or more forms of the same food, for combinations of food, for different units, or for two or more groups for which RDIs are established, the percent DV and quantitative information shall be separated by vertical lines as shown in paragraph (e)(5) of this section.

(4) Nutrient information for vitamins and minerals (except sodium) shall be separated from information on other nutrients by a bar and shall be arrayed vertically in the following order: Vitamin D, calcium, iron, potassium as shown in paragraph (e)(5) of this section.

(5) The following sample label illustrates the provisions of paragraph (e) of this section:

<b>Nutrition Facts</b>			
<b>12 servings per container</b>			
Serving size 1/12 package (44g, about 1/4 cup dry mix)			
<b>Calories</b>	Per 1/4 cup dry mix		Per baked portion
	<b>170</b>		<b>300</b>
	% DV*		% DV*
<b>Total Fat</b>	<b>2%</b>	1.5g	<b>25%</b> 16g
Saturated Fat	<b>5%</b>	1g	<b>25%</b> 5g
Trans Fat		0g	0g
<b>Cholesterol</b>	<b>0%</b>	0mg	<b>20%</b> 60mg
<b>Sodium</b>	<b>13%</b>	300mg	<b>16%</b> 375mg
<b>Total Carbs</b>	<b>12%</b>	36g	<b>12%</b> 36g
Dietary Fiber	<b>2%</b>	<1g	<b>2%</b> <1g
Sugars		18g	18g
Added Sugars		18g	18g
<b>Protein</b>		2g	3g
<b>Vitamin D</b>	0%	0mcg	0% 0mcg
<b>Calcium</b>	8%	100mg	8% 100mg
<b>Iron</b>	6%	1mg	6% 1mg
<b>Potassium</b>	0%	45mg	0% 45mg

\* Footnote on Daily Values (DV) and calories reference to be inserted here.

(6) When dual labeling is presented for a food on a per serving basis and per container basis as required in paragraph (b)(12)(i) of this section or on a per serving basis and per unit basis as required in paragraph (b)(2)(i)(D) of this section, the percent Daily Value as required in paragraph (d)(7)(ii) and the quantitative information by weight shall be presented in two columns, and the percent DV and quantitative information shall be separated by vertical lines as shown in the displays in paragraph (e)(6)(i) of this section.

(i) Nutrient information for vitamins and minerals shall be separated from information on other nutrients by a bar and shall be arrayed vertically in the following order: Vitamin D, calcium, iron, and potassium as shown in the following sample labels.

<b>Nutrition Facts</b>			
<b>2 servings per container</b>			
Serving size		1 cup (255g)	
<b>Calories</b>	<b>Per 1 cup</b>	<b>Per container</b>	
	<b>220</b>	<b>440</b>	
	% DV*		% DV*
<b>Total Fat</b>	<b>8%</b>	5g	<b>15%</b>
Saturated Fat	<b>10%</b>	2g	<b>20%</b>
Trans Fat		0g	
<b>Cholesterol</b>	<b>5%</b>	15mg	<b>10%</b>
<b>Sodium</b>	<b>10%</b>	240mg	<b>21%</b>
<b>Total Carbs</b>	<b>12%</b>	35g	<b>23%</b>
Dietary Fiber	<b>21%</b>	6g	<b>43%</b>
Sugars		7g	
Added Sugars		4g	
<b>Protein</b>		9g	
<b>Vitamin D</b>	25%	5mcg	50%
<b>Calcium</b>	15%	200mg	30%
<b>Iron</b>	6%	1mg	10%
<b>Potassium</b>	10%	470mg	20%

\* Footnote on Daily Values (DV) and calories reference to be inserted here.

<b>Nutrition Facts</b>			
<b>12 servings per container</b>			
Serving size		1/2 Muffin (114g)	
<b>Calories</b>	<b>Per 1/2 muffin</b>	<b>Per 1 muffin</b>	
	<b>380</b>	<b>760</b>	
	% DV*		% DV*
<b>Total Fat</b>	<b>25%</b>	16g	<b>50%</b>
Saturated Fat	<b>15%</b>	3g	<b>30%</b>
Trans Fat		0g	
<b>Cholesterol</b>	<b>17%</b>	50mg	<b>33%</b>
<b>Sodium</b>	<b>21%</b>	480mg	<b>42%</b>
<b>Total Carbs</b>	<b>19%</b>	56g	<b>37%</b>
Dietary Fiber	<b>7%</b>	2g	<b>14%</b>
Sugars		32g	
Added Sugars		30g	
<b>Protein</b>		3g	
<b>Vitamin D</b>	0%	0.1mcg	2%
<b>Calcium</b>	4%	40mg	6%
<b>Iron</b>	10%	2mg	20%
<b>Potassium</b>	4%	190mg	8%

\* Footnote on Daily Values (DV) and calories reference to be inserted here.

(ii) The following sample label illustrates the provisions of paragraphs (b)(2)(i)(D) and (b)(12)(i) of this section for labels that use the tabular display.

<b>Nutrition Facts</b>		Per cup		Per container		Per cup		Per container		* Footnote on Daily Values (DV) and calories reference to be inserted here.	
		% DV*		% DV*		% DV*		% DV*			
<b>2 servings</b>		<b>Total Fat</b>	<b>8%</b>	5g	<b>15%</b>	10g	<b>Total Carbs</b>	<b>12%</b>	35g	<b>23%</b>	70g
Serving size 1 cup (255g)		<b>Saturated Fat</b>	<b>10%</b>	2g	<b>20%</b>	4g	<b>Dietary Fiber</b>	<b>21%</b>	6g	<b>43%</b>	12g
<b>Calories</b>		<b>Trans Fat</b>		0g		0g	<b>Sugars</b>		7g		14g
<b>220</b>	<b>440</b>	<b>Cholesterol</b>	<b>5%</b>	15mg	<b>10%</b>	30mg	<b>Added Sugars</b>		4g		8g
per cup	per container	<b>Sodium</b>	<b>10%</b>	240mg	<b>21%</b>	480mg	<b>Protein</b>		9g		18g
		Vitamin D	25%	5mcg	50%	10mcg	Iron	6%	1mg	10%	2mg
		Calcium	15%	200mg	30%	400mg	Potassium	10%	470mg	20%	940mg

(f) The declaration of nutrition information may be presented in the simplified format set forth herein when a food product contains insignificant amounts of eight or more of the following: Calories, total fat, saturated fat, trans fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, added sugars, protein, vitamin D, calcium, iron, and potassium; except that for foods intended for infants 7 months to 12 months of age and children 1 through 3 years of age to which paragraph (j)(5)(i) of this section applies, nutrition information may be presented in the simplified format when a food product contains insignificant amounts of six or more of the following: Calories, total fat, sodium, total carbohydrate, dietary fiber, sugars, added sugars, protein, vitamin D, calcium, iron, and potassium.

\* \* \* \* \*

(2) \* \* \*

(ii) Any other nutrients identified in paragraph (f) of this section that are present in the food in more than insignificant amounts; and

\* \* \* \* \*

(4) If any nutrients are declared as provided in paragraphs (f)(2)(iii), (f)(2)(iv), or (f)(3) of this section as part of the simplified format or if any nutrition claims are made on the label or in labeling, the statement "Not a significant source of \_\_\_" (with the blank filled in with the

name(s) of any nutrient(s) identified in paragraph (f) of this section that are present in insignificant amounts) shall be included at the bottom of the nutrition label.

<b>Nutrition Facts</b>	
<b>64 servings per container</b>	
Serving size	1 tbsp (14g)
<b>Amount per 1 tablespoon</b>	
<b>Calories</b>	<b>130</b>
% DV*	
<b>22%</b>	<b>Total Fat</b> 14g
<b>10%</b>	<b>Saturated Fat</b> 2g
	<i>Trans</i> Fat 2g
	<b>Polyunsaturated Fat</b> 4g
	<b>Monounsaturated Fat</b> 6g
<b>0%</b>	<b>Sodium</b> 0mg
<b>0%</b>	<b>Total Carbs</b> 0g
	<b>Protein</b> 0g
Not a significant source of cholesterol, dietary fiber, sugars, vitamin D, calcium, iron, and potassium	
* Abbreviated footnote statement to be inserted here.	

(5) Except as provided for in paragraphs (j)(5) and (j)(13) of this section, nutrient information declared in the simplified format shall be presented in the same manner as specified in paragraphs (d) or (e) of this section.

(g) Compliance with this section shall be determined as follows:

\* \* \* \* \*

(2) The sample for nutrient analysis shall consist of a composite of 12 subsamples (consumer units), taken 1 from each of 12 different randomly chosen shipping cases, to be representative of a lot. Unless a particular method of analysis is specified in paragraph (c) of this section, composites shall be analyzed by appropriate methods as given in the "Official Methods of Analysis of the AOAC International," 19th Ed. (2012), which is incorporated by reference in accordance with 5 U.S.C. 552(a) or 1 CFR part 51 or, if no AOAC method is available or

appropriate, by other reliable and appropriate analytical procedures. The availability of this incorporation by reference is given in paragraph (c)(7) of this section.

(3) \* \* \*

(ii) Class II. Naturally occurring (indigenous) nutrients. When a nutrient or nutrients are naturally occurring (indigenous) in an ingredient that is added to a food, the total amount of such nutrient(s) in the final food product is subject to class II requirements, except that when a nutrient or nutrients are not naturally occurring (exogenous) in an ingredient that is added to a food, the total amount of such nutrient(s) in the final food product is subject to class I requirements.

(4) A food with a label declaration of a vitamin, mineral, protein, total carbohydrate, dietary fiber, soluble fiber, insoluble fiber, polyunsaturated or monounsaturated fat shall be deemed to be misbranded under section 403(a) of the Federal Food, Drug, and Cosmetic Act (the act) unless it meets the following requirements:

(i) When a vitamin, mineral, protein, or non-digestible carbohydrate(s) (when the food contains only non-digestible carbohydrates (soluble or insoluble) that meet the definition of dietary fiber) meets the definition of a Class I nutrient, the nutrient content of the composite must be formulated to be at least equal to the value for that nutrient declared on the label.

(ii) When a vitamin, mineral, protein, total carbohydrate, polyunsaturated or monounsaturated fat, or non-digestible carbohydrate(s) (when the food contains only non-digestible carbohydrates (soluble or insoluble) that meet the definition of dietary fiber) meets the definition of a Class II nutrient, the nutrient content of the composite must be at least equal to 80 percent of the value for that nutrient declared on the label. No regulatory action will be based on

a determination of a nutrient value that falls below this level by a factor less than the variability generally recognized for the analytical method used in that food at the level involved.

(5) A food with a label declaration of calories, sugars, added sugars (when the only source of sugars in the food is added sugars), total fat, saturated fat, trans fat, cholesterol, or sodium shall be deemed to be misbranded under section 403(a) of the act if the nutrient content of the composite is greater than 20 percent in excess of the value for that nutrient declared on the label. No regulatory action will be based on a determination of a nutrient value that falls above this level by a factor less than the variability generally recognized for the analytical method used in that food at the level involved.

(6) Reasonable excesses of vitamins, minerals, protein, total carbohydrate, dietary fiber, soluble fiber, insoluble fiber, sugar alcohols, polyunsaturated or monounsaturated fat over labeled amounts are acceptable within current good manufacturing practice. Reasonable deficiencies of calories, sugars, added sugars, total fat, saturated fat, trans fat, cholesterol, or sodium under labeled amounts are acceptable within current good manufacturing practice.

(7) Compliance will be based on the metric measure specified in the label statement of the serving size.

(8) Alternatively, compliance with the provisions set forth in paragraphs (g)(1) through (g)(6) of this section may be provided by use of an FDA approved database that has been computed following FDA guideline procedures and where food samples have been handled in accordance with current good manufacturing practice to prevent nutrition loss. FDA approval of a database shall not be considered granted until the Center for Food Safety and Applied Nutrition has agreed to all aspects of the database in writing. The approval will be granted where a clear need is presented (e.g., raw produce and seafood). Approvals will be in effect for a limited time,

e.g., 10 years, and will be eligible for renewal in the absence of significant changes in agricultural or industry practices. Approval requests shall be submitted in accordance with the provisions of § 10.30 of this chapter. Guidance in the use of databases may be found in the "FDA Nutrition Labeling Manual--A Guide for Developing and Using Data Bases," available from the Office of Nutrition, Labeling, and Dietary Supplements (HFS- 800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740 or by going to <http://www.fda.gov>.

\* \* \* \* \*

(10) The manufacturer must make and keep written records (e.g., analyses of databases, recipes, formulations, or batch records) to verify the declared amount of that nutrient on the Nutrition Facts label as follows:

(i) When a mixture of dietary fiber, and added non-digestible carbohydrate(s) that does not meet the definition of dietary fiber, is present in the food, a manufacturer must make and keep written records of the amount of non-digestible carbohydrate(s) added to the food that does not meet the definition of dietary fiber.

(ii) When a mixture of soluble fiber and added non-digestible carbohydrate(s) that does not meet the definition of dietary fiber is present in the food, a manufacturer must make and keep written records necessary to verify the amount of the non-digestible carbohydrate(s) added to the food that does not meet the definition of dietary fiber.

(iii) When a mixture of insoluble fiber and added non-digestible carbohydrate(s) that does not meet the definition of dietary fiber is present in the food, a manufacturer must make and keep written records necessary to verify the amount of the non-digestible carbohydrate(s) added to the food that does not meet the definition of dietary fiber

(iv) When a mixture of naturally occurring and added sugars is present in the food, a manufacturer must make and keep written records of the amount of added sugars added to the food during the processing of the food, and if packaged as a separate ingredient, as packaged (whether as part of a package containing one or more ingredients or packaged as a single ingredient).

(v) When the amount of added sugars added to yeast-leavened bakery products, wines with less than 7 percent alcohol by volume, or beer that does not meet the definition of a "malt beverage," as defined by the Federal Alcohol Administration Act (27 U.S.C. 211(a)(7)), is reduced through the process of fermentation, manufacturers must:

(A) Make and keep records of all relevant scientific data and information relied upon by the manufacturer that demonstrates the amount of added sugars in the food after fermentation and a narrative explaining why the data and information are sufficient to demonstrate the amount of added sugars declared in the finished food, provided the data and information used is specific to the type of fermented food manufactured; or

(B) Make and keep records of the amount of added sugars added to the food before and during the processing of the food, and if packaged as a separate ingredient, as packaged (whether as part of a package containing one or more ingredients or packaged as a single ingredient) and in no event shall the amount of added sugars declared exceed the amount of total sugars on the label.

(vi) When a mixture of all rac- $\alpha$ -tocopherol acetate and RRR- $\alpha$ -tocopherol is present in a food, manufacturers must make and keep written records of the amount of all rac- $\alpha$ -tocopherol acetate added to the food and RRR- $\alpha$ -tocopherol in the finished food.

(vii) When a mixture of folate and folic acid is present in a food, manufacturers must make and keep written records of the amount of folic acid added to the food and folate in the finished food.

(11) Records necessary to verify certain nutrient declarations that are specified in paragraph (g)(10) of this section must be kept for a period of at least 2 years after introduction or delivery for introduction of the food into interstate commerce. Such records must be provided to FDA upon request, during an inspection, for official review and photocopying or other means of reproduction. Records required to verify information on the label may be kept either as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records which must be kept in accordance with part 11 of this chapter. These records must be accurate, indelible, and legible. Failure to make and keep the records or provide the records to appropriate regulatory authorities, as required by this subparagraph, would result in the food being misbranded under section 403(a)(1) of the act.

(h) \* \* \*

(3) \* \* \*

(iv) Nutrition information may be provided per serving for individual foods in the package, or, alternatively, as a composite per serving for reasonable categories of foods in the package having similar dietary uses and similar significant nutritional characteristics. Reasonable categories of foods may be used only if accepted by FDA. In determining whether a proposed category is reasonable, FDA will consider whether the values of the characterizing nutrients in the foods proposed to be in the category meet the compliance criteria set forth in paragraphs (g)(3) through (g)(6) of this section. Proposals for such categories may be submitted

in writing to the Office of Nutrition, Labeling and Dietary Supplements (HFS-800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740.

\* \* \* \* \*

(4) If a food is commonly combined with other ingredients or is cooked or otherwise prepared before eating, and directions for such combination or preparations are provided, another column of figures may be used to declare nutrition information on the basis of the food as consumed in the format required in paragraph (e) of this section; e.g., a dry ready-to-eat cereal may be described with the percent Daily Value and the quantitative amounts for the cereal as sold (e.g., per ounce), and the percent Daily Value and the quantitative amounts for the cereal and milk as suggested in the label (e.g., per ounce of cereal and ½ cup of vitamin D fortified skim milk); and a cake mix may be labeled with the percent Daily Value and the quantitative amounts for the dry mix (per serving) and the percent Daily Value and the quantitative amounts for the serving of the final cake when prepared, as shown in paragraph (e)(5): Provided, that, the type and quantity of the other ingredients to be added to the product by the user and the specific method of cooking and other preparation shall be specified prominently on the label.

\* \* \* \* \*

(j) \* \* \*

(5)(i) Foods, other than infant formula, represented or purported to be specifically for infants 7 through 12 months and children 1 through 3 years of age shall bear nutrition labeling. The nutrients declared for infants 7 through 12 months and children 1 through 3 years of age shall include calories, total fat, saturated fat, trans fat, cholesterol, sodium, total carbohydrates,

dietary fiber, sugars, added sugars, protein, and the following vitamins and minerals: Vitamin D, calcium, iron, and potassium.

<b>Nutrition Facts</b>	
<b>2 servings per container</b>	
Serving size	1 pack (70g)
Amount per pack	
<b>Calories</b>	<b>25</b>
% DV*	
<b>0%</b>	<b>Total Fat</b> 0g
	Saturated Fat 0g
	Trans Fat 0g
	<b>Cholesterol</b> 0mg
	<b>Sodium</b> 74mg
<b>5%</b>	<b>Total Carbs</b> 5g
	Dietary Fiber 1g
	Sugars 3g
	Added Sugars 0g
<b>0%</b>	<b>Protein</b> 0g
<b>0%</b>	<b>Vitamin D</b> 0mcg
<b>2%</b>	<b>Calcium</b> 5mg
<b>10%</b>	<b>Iron</b> 1mg
<b>35%</b>	<b>Potassium</b> 230mg
* Footnote on Daily Values (DV) to be inserted here.	

(ii) Foods other than infant formula, represented or purported to be specifically for infants 7 through 12 months of age shall bear nutrition labeling, except that:

(A) Such labeling shall not declare a percent Daily Value for saturated fat, trans fat, cholesterol, sodium, dietary fiber, sugars, or added sugars.

\* \* \* \* \*

(13) \* \* \*

(ii) \* \* \*

(A) \* \* \*.

(1) The following sample label illustrates the tabular display for small packages.

<b>Nutrition Facts</b>	% DV* Amount per 1/6 cup	% DV* Amount per 1/6 cup
<b>5 servings</b> Serv. size 1/6 cup (28g) <b>90 Calories</b> Per 1/6 cup	<b>3%</b> <b>Total Fat</b> 2g	<b>5%</b> <b>Carbs</b> 15g
	<b>5%</b> <b>Sat. Fat</b> 1g	<b>0%</b> <b>Diet. Fiber</b> 0g
	<b>Trans Fat</b> 0.5g	<b>Sugars</b> 14g
	<b>3%</b> <b>Cholest.</b> 10mg	<b>Added Sugars</b> 13g
	<b>9%</b> <b>Sodium</b> 200mg	<b>Protein</b> 3g
	<b>0% Vitamin D • 6% Calcium • 6% Iron • 10% Potassium</b>	
	* Insert abbrev. footnote	

(2) The following sample label illustrates the linear display.

<b>Nutrition Facts</b>		<b>Serving size 1 package</b> Amount per package		<b>Calories 45</b>	
2% DV	<b>Total Fat</b> 1g	0% DV	<b>Cholest.</b> 0mg	4% DV	Dietary Fiber 1g
3% DV	Sat. Fat 0.5g	2% DV	<b>Sodium</b> 50mg		Sugars 4g
	Trans Fat 0.5g	3% DV	<b>Total Carbs</b> 8g		Added Sugars 4g
<b>Protein</b> 1g					
0%DV Vitamin D • 0%DV Calcium • 2%DV Iron • 10%DV Potassium					

(B) Using any of the following abbreviations:

Serving size--Serv size

Servings per container--Servings

Calories from saturated fat--Sat fat cal

Saturated fat--Sat fat

Monounsaturated fat--Monounsat fat

Polyunsaturated fat--Polyunsat fat

Cholesterol--Cholest

Total carbohydrate--Total carbs

Dietary fiber--Fiber

Soluble fiber--Sol fiber

Insoluble fiber--Insol fiber

Sugar alcohol--Sugar alc

(C) Omitting the footnote statement and placing another asterisk at the bottom of the label followed by the statement "Percent Daily Values are based on a 2,000 calorie diet."

\* \* \* \* \*

(18) \* \* \*

(iv) A notice shall be filed with the Office of Nutrition, Labeling, and Dietary Supplements (HFS-800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740 and contain the following information, except that if the person is not an importer and has fewer than 10 full-time equivalent employees, that person does not have to file a notice for any food product with annual sales of fewer than 10,000 total units:

\* \* \* \* \*

3. In § 101.36:

a. Revise paragraphs (b)(1)(i), (b)(2)(i) introductory text, (b)(2)(i)(B), (b)(2)(ii)(A), (b)(2)(iii) introductory text, (b)(2)(iii)(D) through (G), (b)(3)(ii)(A), (c)(4), (e) introductory text, (e)(8), (e)(11)(i) through (viii), (e)(12), (f)(2), and (i)(1); and

b. Remove paragraph (i) introductory text.

The revisions read as follows:

§ 101.36 Nutrition labeling of dietary supplements.

\* \* \* \* \*

(b) \* \* \*

(1) Serving size. (i) The subheading "Serving Size" shall be placed under the heading "Supplement Facts" and aligned on the left side of the nutrition label. The subheading "Servings Per Container" and the actual number of servings shall be highlighted in bold or extra bold type. The serving size shall be determined in accordance with §§ 101.9(b) and 101.12(b), table 2. Serving size for dietary supplements shall be expressed using a term that is appropriate for the form of the supplement, such as "tablets," "capsules," "packets," or "teaspoonfuls."

\* \* \* \* \*

(2) \* \* \* (i) The (b)(2)-dietary ingredients to be declared, that is, total calories, total fat, saturated fat, trans fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, added sugars, protein, vitamin D, calcium, iron, and potassium, shall be declared when they are present in a dietary supplement in quantitative amounts by weight that exceed the amount that can be declared as zero in nutrition labeling of foods in accordance with § 101.9(c). Calories from saturated fat, polyunsaturated fat, monounsaturated fat, soluble fiber, insoluble fiber, and sugar alcohol may be declared, but they shall be declared when a claim is made about them. Any (b)(2)-dietary ingredients that are not present, or that are present in amounts that can be declared as zero in § 101.9(c), shall not be declared (e.g., amounts corresponding to less than 2 percent of the RDI for vitamins and minerals). Protein shall not be declared on labels of products that, other than ingredients added solely for technological reasons, contain only individual amino acids.

\* \* \* \* \*

(B) The names of dietary ingredients that are declared under paragraph (b)(2)(i) of this section shall be presented in a column aligned on the left side of the nutritional label in the order and manner of indentation specified in § 101.9(c), except that calcium and iron shall follow pantothenic acid, and sodium and potassium shall follow chloride. This results in the following order for vitamins and minerals: Vitamin A, vitamin C, vitamin D, vitamin E, vitamin K, thiamin, riboflavin, niacin, vitamin B<sub>6</sub>, folic acid, vitamin B<sub>12</sub>, biotin, pantothenic acid, calcium, iron, phosphorous, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, sodium, potassium, and choline. The (b)(2)-dietary ingredients shall be listed according to the nomenclature specified in § 101.9 or in paragraph (b)(2)(i)(B)(2) of this section.

(1) When "Calories" are declared, they shall be listed first in the column of names, beneath a light bar separating the heading "Amount Per Serving" from the list of names. When "Calories from saturated fat" are declared, they shall be indented under "Calories."

(2) The following synonyms may be added in parentheses immediately following the name of these (b)(2)-dietary ingredients: Vitamin C (ascorbic acid), thiamin (vitamin B<sub>1</sub>), riboflavin (vitamin B<sub>2</sub>), and calories (energy). Energy content per serving may be expressed in kilojoule units, added in parentheses immediately following the statement of caloric content.

(3) Beta-carotene may be declared as the percent of vitamin A that is present as beta-carotene, except that the declaration is required when a claim is made about beta-carotene. When declared, the percent shall be declared to the nearest whole percent, immediately adjacent to or beneath the name vitamin A (e.g., "Vitamin A (90% as beta-carotene)"). The amount of beta-carotene in terms of micrograms (mcg) may be included in the parentheses following the percent statement (e.g., "Vitamin A (90% (810 mcg) as beta-carotene)").

(ii) \* \* \*

(A) The amounts shall be expressed in the increments specified in § 101.9(c)(1) through (c)(7), which includes increments for sodium.

\* \* \* \* \*

(iii) The percent of the Daily Value of all dietary ingredients declared under paragraph (b)(2)(i) of this section shall be listed, except that the percent of the Daily Value for protein may be omitted as provided in § 101.9(c)(7); no percent of the Daily Value shall be given for subcomponents for which DRVs or RDIs have not been established (e.g., sugars).

\* \* \* \* \*

(D) If the percent of Daily Value is declared for total fat, saturated fat, total carbohydrate, dietary fiber, or protein, a symbol shall follow the value listed for those nutrients that refers to the same symbol that is placed at the bottom of the nutrition label, below the bar required under paragraph (e)(6) of this section and inside the box, that is followed by the statement "Percent Daily Values are based on a 2,000 calorie diet." If the product is represented or purported to be for use by children 1 through 3 years of age, and if the percent of Daily Value is declared for total fat, total carbohydrate, dietary fiber, or protein, a symbol shall follow the value listed for those nutrients that refers to the same symbol that is placed at the bottom of the nutrition label, below the bar required under paragraph (e)(6) of this section and inside the box, that is followed by the statement "Percent Daily Values are based on a 1,000 calorie diet."

(E) The percent of Daily Value shall be based on RDI or DRV values for adults and children 4 or more years of age, unless the product is represented or purported to be specifically for infants 7 through 12 months of age, children 1 through 3 years of age, or pregnant and lactating women, in which case the column heading shall clearly state the intended group. If the product is for persons within more than one group, the percent of Daily Value for each group shall be presented in separate columns as shown in paragraph (e)(11)(ii) of this section.

(F) For declared subcomponents that have no DRVs or RDIs, a symbol (e.g., an asterisk) shall be placed in the "Percent Daily Value" column that shall refer to the same symbol that is placed at the bottom of the nutrition label, below the last heavy bar and inside the box, and followed by a statement "Daily Value not established."

(G) When calories or calories from saturated fat are declared, the space under the "% DV" column shall be left blank for these items. When there are no other (b)(2)-dietary ingredients listed for which a value must be declared in the "% DV" column, the column may be

omitted as shown in paragraph (e)(11)(vii) of this section. When the "% DV" column is not required, but the dietary ingredients listed are subject to paragraph (b)(2)(iii)(F) of this section, the symbol required in that paragraph shall immediately follow the quantitative amount by weight for each dietary ingredient listed under "Amount Per Serving."

(3) \* \* \*

(ii) \* \* \*

(A) These amounts shall be expressed using metric measures in appropriate units.

\* \* \* \* \*

(c) \* \* \*

(4) The sample label shown in paragraph (e)(11)(v) of this section illustrates one method of nutrition labeling a proprietary blend of dietary ingredients.

\* \* \* \* \*

(e) Except as provided for small and intermediate sized packages under paragraph (i)(2) of this section, information other than the title, headings, and footnotes shall be in uniform type size no smaller than 8 point. A font size at least two points greater shall be used for "Calories" and the heading "Calories" and the actual number of calories per serving shall be highlighted in bold or extra bold type. Type size no smaller than 6 point may be used for column headings (e.g., "Amount Per Serving" and "% Daily Value") and for footnotes (e.g., "Percent Daily Values are based on a 2,000 calorie diet).

\* \* \* \* \*

(8) If the product contains two or more separately packaged dietary supplements that differ from each other (e.g., the product has a packet of supplements to be taken in the morning and a different packet to be taken in the afternoon), the quantitative amounts and percent of

Daily Value may be presented as specified in this paragraph in individual nutrition labels or in one aggregate nutrition label as illustrated in paragraph (e)(11)(iii) of this section.

\* \* \* \* \*

(11) \* \* \*

(i) Multiple vitamins

<b>Supplement Facts</b>		
Serving Size 1 Tablet		
Servings Per Container 100		
	<b>Amount Per Serving</b>	<b>% Daily Value</b>
Vitamin A (as retinyl acetate and 50% as beta-carotene)	900 mcg	100%
Vitamin C (as ascorbic acid)	90 mg	100%
Vitamin D (as cholecalciferol)	20 mcg	100%
Vitamin E (as dl-alpha tocopheryl acetate)	15 mg	100%
Thiamin (as thiamin mononitrate)	1.2 mg	100%
Riboflavin	1.3 mg	100%
Niacin (as niacinamide)	16 mg	100%
Vitamin B <sub>6</sub> (as pyridoxine hydrochloride)	1.7 mg	100%
Folic acid	400 mcg DFE	100%
Vitamin B <sub>12</sub> (as cyanocobalamin)	2.4 mcg	100%
Biotin	3 mcg	10%
Pantothenic Acid (as calcium pantothenate)	5 mg	100%

Other ingredients: Gelatin, lactose, magnesium stearate, microcrystalline cellulose, FD&C Yellow No. 6, propylene glycol, propylparaben, and sodium benzoate.

## (ii) Multiple vitamins for children and adults

<b>Supplement Facts</b>			
Serving Size 1 Tablet Servings Per Container 200			
<b>Amount Per Serving</b>		<b>% Daily Value for Children 1 through 3 Years of Age</b>	<b>% Daily Value for Adults and Children 4 or more Years of Age</b>
Calories	5		
Total Carbohydrate	1 g	<1%**	<1%*
Sugars	1 g	†	†
Added Sugars	1 g	†	†
Vitamin A (50% as beta-carotene)	450 mcg	150%	50%
Vitamin C	60 mg	400%	67%
Vitamin D	20 mcg	133%	100%
Vitamin E	8 mg	133%	53%
Thiamin	0.9 mg	180%	75%
Riboflavin	0.9 mg	180%	69%
Niacin	11.2 mg	187%	70%
Vitamin B <sub>6</sub>	0.9 mg	180%	53%
Folic acid	300 mcg DFE	200%	75%
Vitamin B <sub>12</sub>	2.0 mcg	222%	83%

\* Percent Daily Values are based on a 2,000 calorie diet.  
\*\* Percent Daily Values are based on a 1,000 calorie diet.  
† Daily Value not established.

Other ingredients: Sucrose, sodium ascorbate, gelatin, maltodextrin, artificial flavors, dl-alpha tocopheryl acetate, niacinamide, magnesium stearate, Yellow 6, artificial colors, stearic acid, palmitic acid, pyridoxine hydrochloride, thiamin mononitrate, vitamin A acetate, cholecalciferol, and cyanocobalamin.

## (iii) Multiple vitamins in packets

<b>Supplement Facts</b>				
Serving Size 1 Packet Servings Per Container 10				
<b>Amount Per Serving</b>	<b>AM Packet</b>		<b>PM Packet</b>	
	<b>% Daily Value</b>		<b>% Daily Value</b>	
Vitamin A	450 mcg	50%	450 mcg	50%
Vitamin C	90 mg	100%	90 mg	100%
Vitamin D	20 mcg	100%		
Vitamin E	15 mg	100%		
Thiamin	1.2 mg	100%	1.2 mg	100%
Riboflavin	1.3 mg	100%	1.3 mg	100%
Niacin	16 mg	100%	16 mg	100%
Vitamin B <sub>6</sub>	1.7 mg	100%	1.7 mg	100%
Folic Acid	200 mcg DFE	50%	200 mcg DFE	50%
Vitamin B <sub>12</sub>	1.2 mcg	50%	1.2 mcg	50%
Biotin			3 mcg	10%
Pantothenic Acid	2.5 mg	50%	2.5 mg	50%

Ingredients: Sodium ascorbate, ascorbic acid, calcium pantothenate, niacinamide, dl-alpha tocopheryl acetate, microcrystalline cellulose, artificial flavors, dextrin, starch, mono- and diglycerides, vitamin A acetate, magnesium stearate, gelatin, FD&C Blue #1, FD&C Red #3, artificial colors, thiamin mononitrate, pyridoxine hydrochloride, citric acid, lactose, sorbic acid, tricalcium phosphate, sodium benzoate, sodium caseinate, methylparaben, potassium sorbate, BHA, BHT, ergocalciferol, and cyanocobalamin.

(iv) Dietary supplement containing dietary ingredient with and without RDIs and DRVs

<b>Supplement Facts</b>	
Serving Size 1 Capsule	
Servings Per Container 100	
<b>Amount Per Capsule</b>	<b>% Daily Value</b>
Calories 20	
Total Fat 2 g	3%*
Saturated Fat 0.5 g	3%*
<i>Trans</i> Fat 0 g	†
Polyunsaturated Fat 1 g	†
Monounsaturated Fat 0.5 g	†
Vitamin A 765 mcg	85%
Vitamin D 21 mcg	105%
Omega-3 fatty acids 0.5 g	†
* Percent Daily Values are based on a 2,000 calorie diet.	
† Daily Value not established.	

Ingredients: Cod liver oil, gelatin, water, and glycerin.

(v) A proprietary blend of dietary ingredients

<b>Supplement Facts</b>		
Serving Size 1 tsp (3g) (makes 8 fl oz prepared)		
Servings Per Container 24		
	<b>Amount Per Teaspoon</b>	<b>% Daily Value</b>
Calories	10	
Total Carbohydrate	2 g	<1%*
Sugars	2 g	†
Added Sugars	2 g	†
Proprietary Blend	0.7 g	†
German Chamomile (flower)		†
Hyssop (leaves)		†
* Percent Daily Values are based on a 2,000 calorie diet.		
† Daily Value not established.		

Other ingredients: Fructose, lactose, starch, and stearic acid.

(vi) Dietary supplement of an herb

<b>Supplement Facts</b>	
Serving Size 1 Capsule	
Servings Per Container 100	
<b>Amount Per Capsule</b>	
Oriental Ginseng, powdered (root)	250 mcg*
* Daily Value not established.	

Other ingredients: Gelatin, water, and glycerin.

(vii) Dietary supplement of amino acids

<b>Supplement Facts</b>	
Serving Size 1 Tablet	
Servings Per Container 50	
<b>Amount Per Tablet</b>	
Calories	15
Isoleucine (as L-isoleucine hydrochloride)	450 mg*
Leucine (as L-leucine hydrochloride)	620 mg*
Lysine (as L-lysine hydrochloride)	500 mg*
Methionine (as L-methionine hydrochloride)	350 mg*
Cystine (as L-cystine hydrochloride)	200 mg*
Phenylalanine (as L-phenylalanine hydrochloride)	220 mg*
Tyrosine (as L-tyrosine hydrochloride)	900 mg*
Threonine (as L-threonine hydrochloride)	300 mg*
Valine (as L-valine hydrochloride)	650 mg*
* Daily Value not established.	

Other ingredients: Cellulose, lactose, and magnesium stearate.

(viii) Dietary supplement illustrating “per serving” and “per day” information

<b>Supplement Facts</b>				
Serving Size 1 Tablet Servings Per Container 100				
	<b>Per Caplet</b>		<b>Per Day (3 Caplets)</b>	
	<b>Amount</b>	<b>% Daily Value</b>	<b>Amount</b>	<b>% Daily Value</b>
Vitamin D (as cholecalciferol)	7 mcg	35%	21 mcg	105%
Calcium (as calcium citrate)	650 mg	50%	1950 mg	150%

Other ingredients: Hydroxypropylmethylcellulose (HPMC), microcrystalline cellulose, maltodextrin, and magnesium stearate.

(12) If space is not adequate to list the required information as shown in the sample labels in paragraph (e)(11) of this section, the list may be split and continued to the right as long as the headings are repeated. The list to the right must be set off by a line that distinguishes it and sets it apart from the dietary ingredients and percent of Daily Value information given to the left. The following sample label illustrates this display:

(12) Split display

# Supplement Facts

Serving Size 1 Packet  
Servings Per Container 10

Amount Per Packet	% Daily Value	Amount Per Packet	% Daily Value
Vitamin A (from cod liver oil)	900 mcg	Zinc (as zinc oxide)	11 mg
Vitamin C (as ascorbic acid)	250 mg	Selenium (as sodium selenate)	25 mcg
Vitamin D (as ergocalciferol)	20 mcg	Copper (as cupric oxide)	0.5 mg
Vitamin E (as dl-alpha tocopherol)	75 mg	Manganese (as manganese sulfate)	5 mg
Thiamin (as thiamin mononitrate)	60 mg	Chromium (as chromium chloride)	50 mcg
Riboflavin	60 mg	Molybdenum (as sodium molybdate)	50 mcg
Niacin (as niacinamide)	60 mg	Potassium (as potassium chloride)	10 mg
Vitamin B <sub>6</sub> (as pyridoxine hydrochloride)	60 mg	Choline (as choline chloride)	100 mg
Folic acid	400 mcg DFE	Betaine (as betaine hydrochloride)	25 mg
Vitamin B <sub>12</sub> (as cyanocobalamin)	100 mcg	Glutamic Acid (as L-glutamic acid)	25 mg
Biotin	100 mcg	Inositol (as inositol monophosphate)	75 mg
Pantothenic Acid (as calcium pantothenate)	60 mg	<i>para</i> -Aminobenzoic acid	30 mg
Calcium (from oystershell)	130 mg	Deoxyribonucleic acid	50 mg
Iron (as ferrous fumarate)	10 mg	Boron	500 mcg
Iodine (from kelp)	150 mcg		
Magnesium (as magnesium oxide)	63 mg		

\* Daily Value not established.

Other ingredients: Cellulose, stearic acid, and silica.

(f) \* \* \*

(2) When it is not technologically feasible, or some other circumstance makes it impracticable, for firms to comply with the requirements of this section, FDA may permit alternative means of compliance or additional exemptions to deal with the situation in accordance with § 101.9(g)(9). Firms in need of such special allowances shall make their request in writing to the Office of Nutrition, Labeling and Dietary Supplements (HFS-800), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740.

\* \* \* \* \*

(i)(1) Dietary supplements are subject to the special labeling provisions specified in § 101.9(j)(5)(i) for foods other than infant formula, represented or purported to be specifically for infants and children less than 2 years of age.

\* \* \* \* \*

Dated: February 24, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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